

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

BEST MEDICAL INTERNATIONAL,
INC.

Plaintiff,

v.

ACCURAY, INC.

Defendant.

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Case No. 2:10-CV-1043-TFM

Gale R. Peterson, Special Master

SPECIAL MASTER'S REPORT AND RECOMMENDATION ON CLAIM
CONSTRUCTION

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I. Introduction

A. Background

Best Medical International Inc. (“Best Medical”) asserts U.S. Patent No. 6,038,283, entitled “Planning Method and Apparatus for Radiation Dosimetry” (the “‘283 patent”). The ‘283 patent generally relates to “a method and apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient.” *Abstract*. Best Medical contends that Accuray, Inc. (“Accuray”) infringes claims 25 and 29 of the ‘283 patent. The parties dispute the overall scope of claim 25 and the meaning of certain claim terms in claim 25, as well as whether claims 25 and 29 are indefinite under 35 U.S.C. § 112 ¶ 2.

B. Referral to the Special Master

On May 13, 2011, the Court appointed the undersigned to serve as special master for conducting a Claim Construction Hearing and preparing a Report and Recommendation to the Court. *See* Order of Court Appointing Special Master dated May 13, 2011 [Dkt. No. 56].

C. The Parties’ Submissions

The parties have filed or provided the following submissions setting out their respective proposed constructions and arguments:

Date Filed	Dkt. No.	Submission
February 7, 2012	131	Joint Disputed Claim Terms/Phrases Chart Appendix B to Local Patent Rules (“JCC”)
March 8, 2012	134	Best Medical’s Opening Claim Construction Brief (“Best Medical’s Brief”)
March 8, 2012	135	Best Medical’s Identification of Extrinsic Evidence (“Best Medical’s Extrinsic Evidence”)
March 29, 2012	138	Accuray’s Responsive Claim Construction Brief (“Accuray’s Response”)
March 29, 2012	139	Accuray’s Identification of Extrinsic Evidence Pursuant to Local Patent Rule 4.3 (“Accuray’s Extrinsic Evidence”)

Date Filed	Dkt. No.	Submission
April 12, 2012	142	Best Medical's Reply to Accuray's Responsive Claim Construction Brief and Notice of Objections to Accuray's Identification of Extrinsic Evidence ("Best Medical's Reply")
April 26, 2012	146	Accuray's Sur-Reply Claim Construction Brief ("Accuray's Sur-Reply")
May 16, 2012		Best Medical's Technology Tutorial Slides
May 16, 2012		Best Medical's Claim Construction Slides
May 16, 2012		Accuray's Technology Tutorial Slides
May 16, 2012		Accuray's Claim Construction Slides

On May 16, 2012, the master conducted a claim construction hearing in the courtroom of The Honorable Terrence McVerry ("*Markman* Hearing"), during which the parties substantially narrowed the issues addressed in their briefing. A transcript of the hearing has been prepared ("*Markman* Tr.").

II. Claim Construction Principles

A. Overview

A patent is a fully integrated written instrument. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). A patent, by statute, must provide a written description of the invention, a disclosure that would enable one of ordinary skill in the art to make and use the invention, and a disclosure of the best mode known to the inventor for practicing the invention. *See* 35 U.S.C. § 112(1).¹ A patent must also contain claims "particularly

¹ 35 U.S.C. § 112(1) provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112(2).² The claims of a patent provide the measure of a patentee’s right to exclude others from practicing the claimed invention. *See* 35 U.S.C. § 154.³

B. The Claims

Primary claim construction principles are discussed and explained in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). Among those are that “[i]t is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’ ” *Id.* at 1312, quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004), and citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). *See also Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998) (claim construction “begins and ends” with the actual words of the claims). “That principle has been recognized since at least 1836, when Congress first required that the specification include a portion in which the inventor ‘shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery.’ ” *Phillips*, 415 F.3d at 1312.

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

² 35 U.S.C. § 112(2) provides:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

³ 35 U.S.C. § 154(a)(1) provides:

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

“[T]he words of a claim ‘are generally given their ordinary and customary meaning,’ ” and “the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application.” *Id.* at 1313. “That starting point is based on the well-settled understanding that inventors are typically persons skilled in the field of the invention and that patents are addressed to and intended to be read by others of skill in the pertinent art.” *Id.* at 1313. “Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.*

“In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314. Thus, in some instances, “general purpose dictionaries may be helpful,” but, as the court explained, “[i]n many cases that give rise to litigation * * * determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art.” *Id.* at 1314; *see Mangosoft, Inc. v. Oracle Corp.*, 525 F.3d 1327, 1333 (Fed. Cir. 2008) (“when considered in the context of and not divorced from the intrinsic evidence, there is nothing improper about referencing [a] definition in correctly construing the claim.”). “Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to ‘those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.’ ” *Id.*, *quoting Innova/Pure Water*, 381 F.3d at 1116. “ ‘Those sources include ‘the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.’ ” *Phillips*, 415 F.3d at 1314.

Thus, the claim construction process begins with the language used in the claims because “[q]uite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms.” *Id.* “Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term. Because claim terms are normally used consistently throughout the

patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Id.* (citation omitted).

“Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.” *Id.* That is referred to as “claim differentiation.” “For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15.

C. The Specification

The specification nevertheless remains important in claim construction. “The claims, of course, do not stand alone. Rather, they are part of ‘a fully integrated written instrument,’ consisting principally of a specification that concludes with the claims. For that reason, claims ‘must be read in view of the specification, of which they are a part.’ * * * [T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* at 1315, *quoting Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d at 1576, 1582.

In particular, “[c]onsistent with that general principle,” the cases recognize that (1) “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs,” and (2) “[i]n other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor’s intention, as expressed in the specification, is regarded as dispositive.” *Id.* at 1316.

However, two claim construction principles are: (1) claims are read in light of the specification, but (2) limitations from the specification must not be read into the claims. The line between the two is not always clear. *See Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed. Cir. 1998) (“[T]here is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.”). In *Phillips*, the Federal Circuit advised that the “line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court’s focus remains on understanding how a person of ordinary skill in the art would understand the claim terms. For instance, although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be

construed as being limited to that embodiment. That is not just because section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant, but also because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.” *Phillips*, 415 F.3d at 1323 (citations omitted).

The Federal Circuit also advised: “[t]o avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent.” *Id.* at 1323 (citations omitted).

Nevertheless, the Federal Circuit has acknowledged that, “[i]n the end, there will still remain some cases in which it will be hard to determine whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature. While that task may present difficulties in some cases, we nonetheless believe that attempting to resolve that problem in the context of the particular patent is likely to capture the scope of the actual invention more accurately than either strictly limiting the scope of the claims to the embodiments disclosed in the specification or divorcing the claim language from the specification.” *Id.* at 1323-24.

D. The Prosecution History

The words in the claim may also be interpreted in light of the prosecution history, if in evidence. See *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). “Like the specification, the prosecution history provides evidence of how the [United States Patent and Trademark Office (“PTO”)] and the inventor understood the patent. Furthermore, like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent.” *Phillips*, 415 F.3d at 1317 (citations omitted).

“Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the

specification and thus is less useful for claim construction purposes.” *Id.* “Nonetheless, the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

E. Means-Plus-Function Limitations

Under § 112(6):

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Section 112(6) thus allows “an applicant [to] describe an element of his invention by the result accomplished or the function served, rather than describing the item or element to be used * * *.” *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 27 (1997). Congress added this language to the Patent Act of 1952 to overcome restrictions imposed by *Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1, 9 (1946). See P.J. Federico, *Commentary on the New Patent Act*, Preface to 35 U.S.C.A. (1954) (reprinted at 75, J. Pat. & Trademark Off. Soc. 161 (1993)).

The general hallmarks of a means-plus-function element are: (1) the element is expressed in terms using the words “means” or “step,” which raises a presumption of an intent to invoke § 112(6), *Al-Site Corp. v. VSL Int’l, Inc.*, 174 F.3d 1308, 1318 (Fed. Cir. 1999) (“[i]f the word ‘means’ appears in a claim element in combination with a function, it is presumed to be a means-plus-function element”); see also *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1584 (Fed. Cir. 1996); (2) a specified function follows the “means” or “step” and is linked to the “means” or “step,” *York Products, Inc. v. Central Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1574 (Fed. Cir. 1996), see also *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc. and Vector Corp.*, 239 F.3d 1225, 1232 (Fed. Cir. 2001) (stating that “a limitation that uses the word ‘means’ but does not recite a function that corresponds to the means does not invoke § 112, ¶ 6”); and (3) there is insufficient structure, material, or acts set out in the claim for achieving the specified function. *Apex v. Raritan*, 325 F.3d 1364, 1372 (Fed. Cir. 2003); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 530-31 (Fed. Cir. 1996), *cert. denied*, 522 U.S. 812 (1997). “Means-plus-function” limitations are construed, as required by § 112(6), to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. *In re Donaldson*, 16 F.3d 1189 (Fed. Cir. 1994)(*en banc*). Those “equivalents” are frequently referred to as “statutory

equivalents” to differentiate other types of “equivalents,” such as those available under the doctrine of equivalents.

The Court must decide as a matter of law whether a particular term or phrase is governed by § 112(6). *Personalized Media Communications LLC v. United States Int’l Trade Comm’n*, 161 F.3d 696, 702 (Fed. Cir. 1998); *Rodime PLC v. Seagate Technology, Inc.*, 174 F.3d 1294 (Fed. Cir. 1999), *cert. denied*, 528 U.S. 1115 (2000).

“Once a court concludes that a claim limitation is a means-plus-function limitation, two steps of claim construction remain: 1) the court must first identify the function of the limitation; and 2) the court must then look to the specification and identify the corresponding structure for that function.” *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 950 (Fed. Cir. 2007); *see also Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1333 (Fed. Cir. 2006). “The determination of the claimed function and corresponding structure of a means-plus-function claim limitation is a question of law, reviewed de novo.” *ACTV Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1087 (Fed. Cir. 2003). Thus, *Markman*-type claim construction of a means-plus-function limitation requires that the Court first identify the stated function and, secondly, identify the corresponding structure, material, or acts described in the specification that is clearly linked to or associated with that function.

The Federal Circuit has emphasized that in performing the first step, “a court may not construe a means-plus-function limitation ‘by adopting a function different from that explicitly recited in the claim.’ ” *JVW Enterprises, Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1331 (Fed. Cir. 2005), *quoting Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999). That is because “[a]n error in identification of the function can improperly alter the identification of structure in the specification corresponding to that function.” *Id.* at 1258.

The Federal Circuit has explained that “[w]e consult the claim language to determine the function of the limitation*** We then consult the written description to determine the corresponding structure necessary to accomplish the stated function.” *Gemstar-TV Guide Int’l, Inc. v. United States Int’l Trade Comm’n*, 383 F.3d 1352, 1361 (Fed. Cir. 2004) (citations and paragraphing omitted). The stated function is that explicitly recited in the claim. *Micro Chem. Inc.*, 194 F.3d at 1250, 1258 (although § 112(6) “requires both identification of the claimed function and identification of the structure in the written description necessary to perform that function,” the “statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim,” nor “does the statute permit incorporation of structure

from the written description beyond that necessary to perform the claimed function.”); *Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 249 F.3d 1314, 1324 (Fed. Cir. 2001) (a means-plus-function limitation cannot be broadened by “reading out” a function). *See generally, Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003); *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1375 (Fed. Cir. 2003); *Overhead Door Corp. v. Chamberlain Group, Inc.*, 194 F.3d 1261 (Fed. Cir. 1999); *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1306 (Fed. Cir. 1998).

After determining the claimed function, the Court must identify the “corresponding structure” in the specification that is “clearly linked” to the recited function. *Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc.*, 248 F.3d 1303, 1311 (Fed. Cir. 2001) (quotes omitted) (“Structure disclosed in the specification is ‘corresponding’ structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim,” quoting *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997); *see also Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346, 1352 (Fed. Cir. 2003) (“Under section 112, paragraph 6, structure disclosed in the specification is ‘corresponding’ structure ‘only if the specification or the prosecution history clearly links or associates that structure to the function recited in the claim.’ ”).

“While corresponding structure need not include all things necessary to enable the claimed invention to work, it must include all structure that actually performs the recited function.” *Default Proof Credit Card System, Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1298 (Fed. Cir. 2005), *citing Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1119 (Fed. Cir. 2002). On the other hand, “a court may not import into the claim structural limitations from the written description that are unnecessary to perform the claimed function.” *Acromed Corp. v. Sofamor Danek Group*, 253 F.3d 1371, 1382 (Fed. Cir. 2001); *Micro Chem, Inc.*, 194 F.3d at 1258 (“The statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim. Nor does the statute permit incorporation of structure from the written description beyond that necessary to perform the claimed function.”). “When multiple embodiments in the specification correspond to the claimed function, proper application of § 112, ¶ 6 generally reads the claim element to embrace each of those embodiments.” *Micro Chem, Inc.*, 194 F.3d at 1258.

The Federal Circuit has advised that the specification must be read as a whole to determine the structure for performing the claimed function. *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1379-80 (Fed. Cir. 2001) (citations omitted) (“The specification must be read as a whole to determine the structure capable of performing the claimed function. In construing terms used in

patent claims, it is necessary to consider the specification as a whole, and to read all portions of the written description, if possible, in a manner that renders the patent internally consistent. In addition, it is important to construe claim language through the ‘viewing glass’ of a person skilled in the art.”). However, the Federal Circuit has also cautioned that structure identified as “corresponding structure” must actually perform the recited function, rather than merely enable the pertinent structure to perform the recited function. *Asyst Techs., Inc. v. Empak, Inc.*, 268 F.3d 1364, 1371 (Fed. Cir. 2001) (“The corresponding structure to a function set forth in a means-plus-function limitation must actually perform the recited function, not merely enable the pertinent structure to operate as intended * * *.”).

Under the terms of § 112(6), a means-plus-function limitation should therefore be construed to cover that corresponding structure and statutory equivalents thereof.

III. The ‘283 Patent

A. Overview

The following abbreviated general description of the ‘283 patent is intended solely as that, and should not be construed as adopting one party’s or the other’s views *vis-à-vis* claim construction. The ‘283 patent, which issued to Mark P. Carol, Robert C. Campbell, Bruce Curran, Richard W. Huber and Richard V. Nash, includes 47 claims, of which claims 1, 14, 18, 22, 25, 29, 33, 36 and 40 are independent. The ‘283 patent claims the benefit of U.S. Provisional Application No. 60/029,488, entitled “Planning Method and Apparatus for Radiation Dosimetry” filed October 24, 1996.

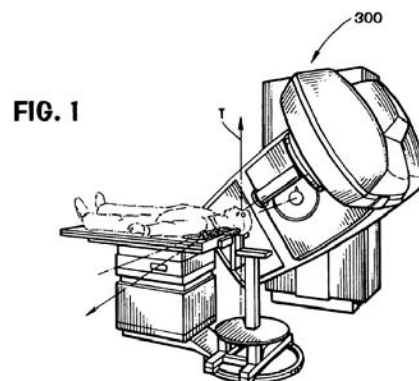
The ‘283 patent explains that “the invention relates to a method and apparatus for conformal radiation therapy of tumors with a radiation beam having a pre-determined, constant beam intensity.” Col. 1, lines 10-12. Generally speaking, the ‘283 patent is drawn to “[a] method and apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient.” *Abstract*. The method and apparatus are said to use “an iterative cost function based on a comparison of desired partial volume data, which may be represented by cumulative dose volume histograms and proposed partial volume data, which may be represented by cumulative dose volume histograms for target tumors and tissue structures for delivery of the optimized radiation beam arrangement.” *Abstract*.

The optimized radiation beam arrangement may then be delivered to the patient by “a conformal radiation therapy apparatus.” *Abstract*.

B. Background

According to the section of the ‘283 patent entitled “Description of the Prior Art,” “[m]odern day radiation therapy of tumors has two goals: eradication of the tumor and avoidance of damage to healthy tissue and organs present near the tumor.” Col. 1, lines 14-16. That is, the “goal of conformal radiation therapy is to confine the delivered radiation dose to only the tumor volume defined by the outer surfaces of the tumor, while minimizing the dose of radiation to surrounding healthy tissue or adjacent healthy organs.” Col. 1, lines 23-27.

According to the ‘283 patent, “[c]onformal radiation therapy * * * typically uses a linear accelerator (‘LINAC’) as the source of the radiation beam used to treat the tumor.” Col. 1, lines 28-31. Figure 1 is said to show “a perspective view of a conventional linear accelerator, including a rotatable couch, collimator and gantry.” Col. 8, lines 33-35.



“The [LINAC] typically has a radiation beam source which is rotated about the patient and directs the radiation beam toward the tumor to be treated. The beam intensity of the radiation beam is a predetermined, constant beam intensity.” Col. 1, lines 31-35.

“Conformal radiation therapy has been traditionally approached through a range of techniques * * *.” Col. 1, lines 28-29. According to the ‘283 patent, “[m]ultileaf collimators, which have multiple leaf, or finger, projections which can be moved individually into and out of the path of the radiation beam, can be programmed to follow the spatial contour of the tumor as seen by the radiation beam as it passes through the tumor, or the ‘beam’s eye view’ of the tumor during the rotation of the radiation beam source, which is mounted on a rotatable gantry of the linear accelerator.” Col. 1, lines 35-43. “The multiple leaves of the multileaf collimator form an outline of

the tumor shape as presented by the tumor volume in the direction of the path of travel of the radiation beam, and thus block the transmission of radiation to tissue disposed outside the tumor's spatial outline as presented to the radiation beam, depending upon the beam's particular radial orientation with respect to the tumor volume." Col. 1, lines 43-49.

Another approach to conformal radiation therapy treatment has been the use of "independently controlled collimator jaws which can scan a slit field across a stationary patient at the same time that a separate set of collimator jaws follows the target volume as the gantry of the linear accelerator rotates." Col. 1, lines 50-54. "A further approach for conformal radiation therapy treatment has been the use of a narrow pencil beam of high energy photons, whose energy can be varied, and the beam is scanned over the tumor target volume so as to deliver the best possible radiation dose distribution in each orientation of the gantry upon which the photon beam source is mounted." Col. 1, lines 59-64.

However, those apparatus and associated methods apparently encounter a "major problem" when the "tumor volume has concave borders, or surfaces," because "varying the spatial configuration, or contour, of the radiation beam, is only successful part of the time." Col. 1, line 66—col. 2, line 3. "[H]ealthy tissue or organs may be disposed within the concavities formed by the outer tumor concave surfaces, as well as the fact that the thickness of the tumor varies along the path of the radiation beam." Col. 2, lines 6-9. The '283 patent explains that "it is necessary to vary the intensity of the radiation beam across the surface of the tumor, as well as vary the outer configuration of the beam to conform to the shape of the tumor presented to the radiation beam." Col. 2, lines 11-14. "For example, where the radiation beam is to pass through a thick section of the tumor, the beam intensity should be higher than when the radiation beam passes through a thin section of the tumor." Col. 2, lines 18-21. "Dedicated scanning beam therapy machines have been developed," in which "beam intensity" is "modulated by increasing the power of its electron gun generating the beam." Col. 2, lines 22-27. Such devices, according to the '283 patent, "are expensive and quite time consuming to use." Col. 2, lines 35-37. "Other methods and apparatus * * * have been developed that spatially modulate the beam intensity" but were also said to be time-consuming to use. Col. 2, lines 41-58.

The '283 patent explains that those "methods and apparatus are designed to minimize the portion of the structures being exposed to radiation." However, the '283 patent states, "[b]ecause exposure to structures surrounding the tumor cannot be completely prevented, treatment plans are

desired that are optimized to eradicate the tumor volume while minimizing the amounts of radiation delivered to the surrounding structures.” Col. 3, lines 9-12. But, the ‘283 patent explains, “[e]xisting methods and apparatus for optimizing treatment plans” have “proven to be insufficient.” Col. 3, lines 12-16.

Existing methods and apparatus are said to use a “computational method of establishing optimized treatment plans based on an objective cost function that attributes costs of radiation of various portions of both the tumor and surrounding tissues, or structures.” Col. 3, lines 17-22. The ‘283 patent states that “[o]ne such computational method is known in the art as simulated annealing.” Col. 3, lines 21-22. The ‘283 patent explains that “[e]xisting simulated annealing methods utilize cost functions that consider the costs of under-exposure of tumor volumes relative to over-exposure of surrounding structures.” Col. 3, lines 22-25. “However, the cost functions used in existing methods do not account for the structure volumes as a whole,” and “do not account for such varying costs associated with the different types of structures.” Col. 3, lines 25-30. “Further, existing methods and apparatus do not allow the physician to utilize the familiar partial volume data associated with Cumulative Dose Volume Histogram (‘CDVH’) curves in establishing the desired dose distributions.” Col. 3, lines 48-52.

C. Description

In the section entitled “Detailed Description of the Invention,” the ‘283 patent discloses an “optimizer,” a “system” that “includes an improved optimized treatment planning system,” and an “optimization method.”

The “optimizer” is said to “compute[] an optimized treatment plan, or beam arrangement, which should be understood to include either the optimal beam positions around the treatment field, the optimal array of beam weights, or beam intensities, otherwise known as an intensity map or fluence profile, or both.” Col. 9, lines 29-34. According to the ‘283 patent:

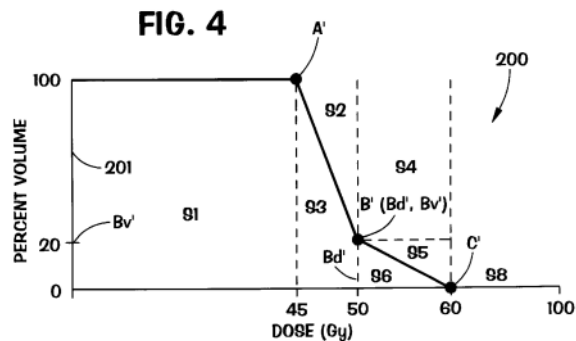
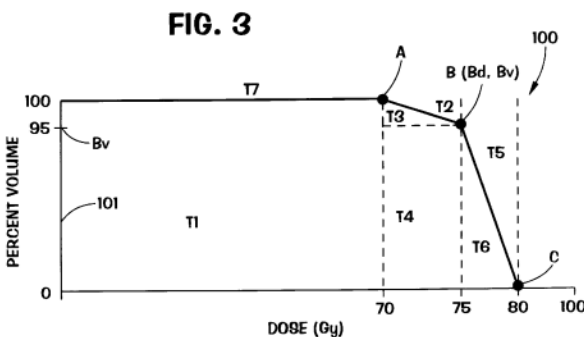
[t]he optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose. At each iteration, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures. If the increase or decrease in beam weights would lead to a greater correspondence to the desired prescription, the change is accepted.

Col. 9, lines 34-45. The '283 patent explains that “[u]ltimately, the SARP [Simulated Annealing Radiotherapy Planning] method will produce an optimize treatment plan, based on the treatment objectives as expressed by the cost function incorporated in the SARP algorithm.” Col. 9, lines 45-48. “Simulated annealing radiotherapy planning (“SARP”) methods are well known in the art to compute optimized radiation beam arrangements to meet objective parameters of a physician with regard to conflicting treatment objectives of a tumor volume and its surrounding structures.” Col. 8, lines 62-65.

The '283 patent explains that the “improved optimized treatment planning system” “accounts for multiple treatment parameters for both a target and multiple surrounding structure types.” Col. 9, lines 49-52. The “system” is said to include “a modified cost function, which allows a physician to use conventional cumulative dose volume histograms (“CDVHs”) to establish a desired prescription of dosage to both the target volume, or target, and each involved structure volume, or structure, which will then be used as input for the system for determining the proposed radiation dose distribution for delivery to the patient.” Col. 9, lines 52-59.

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According to the '283 patent, "partial volume data generally describes what percent of the volume of a tumor or structure can receive how much dose." Col. 10, lines 60-62. "[P]artial volume data *** may include data corresponding to values represented as data points on a *** CDVH curve 100." Col. 10, lines 64-66. Figures 3 and 4 are said to "show conventional target and structure CDVH curves 100, 200, respectively, which are typically used by a physician in reviewing the effect a given dose distribution will have on a target or structure before that dose distribution is applied to the patient." Col. 10, lines 35-39. The '283 patent notes that "[p]hysicians and those skilled in the art or radiation dosimetry are familiar with CDVH curves 100, 200." Col. 10, lines 39-41. The CDVH curves 100, 200 shown in Figures 3 and 4 "are created from partial volume data." Col. 10, lines 53-55.



The '283 patent states that CDVH curves "are typically used to analyze a dose distribution after a treatment plan has been optimized." Col. 10, lines 41-43. However, the '283 patent explains that "[i]n contrast, the familiar CDVH curves 100, 200 are used by a physician using the system of the present invention not only in the Output Process step 807 (FIG. 2), discussed hereinafter in detail, but also prior to the Plan Optimization step 803 (Fig. 2)," also discussed below. Col. 10, lines 43-47.

Regarding the CDVH curve "data points," for example, in the point "B (Bd, Bv)" of Figure 3, "Bd" "is the desired dose to be achieved in the target volume," and "Bv" represents "the portion of the target volume which should have a dose greater than the goal." Col. 10, line 65-col. 11, line 6. Areas above and below the curves (T1-T7 and S1-S6, and S8, in Figures 3 and 4, respectively) are described as "zones" of the CDVH curve which may be assigned "[r]elative weights *** that will achieve the desired objective of each type of target or structure when applied by the cost function of the present invention." Col. 12, lines 53-55.

For instance, in one implementation of the invention, sparing of sensitive structures is preferred over treating the entire target in order to avoid

complications which can result from the delivery of radiation. Sparing of sensitive structures is accomplished by delivering a dose distribution whereby the proposed structure CDVH curve, or structure pseudo-curve is equivalent to or better than the desired structure CDVH curve. In order to achieve this result, weights must be picked so that if a beam change is made that improves the proposed target CDVH curve, or target pseudo-curves, but worsens the proposed structure CDVH curves, or structure pseudo-curves, the change will be rejected.

Col. 13, lines 60-col. 14, line 4.

Regarding the “optimization method,” the ‘283 patent notes that “[t]he optimization method may be carried out using conventional equipment, including a conventional [LINAC], having a rotatable gantry, a conventional computer or set of computers, and plan optimization software, which utilizes the optimization method of the present invention.” Col. 9, lines 59-64. Figure 1 (reproduced above) is said to show a perspective view of a “conventional linear accelerator (‘LINAC’).” The ‘283 patent explains that “[m]odern LINACs radiate a tumor site by making multiple passes along varying arcs approaching the target volume along different entrance paths, each arc being directed toward a point central to a target volume, commonly referred to as an epicenter of the treatment volume.” Col. 8, line 67-col. 9, line 2. “By utilizing such multiple beam passes, certain portions of the treatment field are irradiated by only some of the beam arcs while other portions of the treatment field are radiated by each beam arc * * *.” Col. 9, lines 7-10.

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Figure 2 is said to “show[] a procedure for creating a treatment plan utilizing the system of the present invention.” Col. 9, lines 65-66.

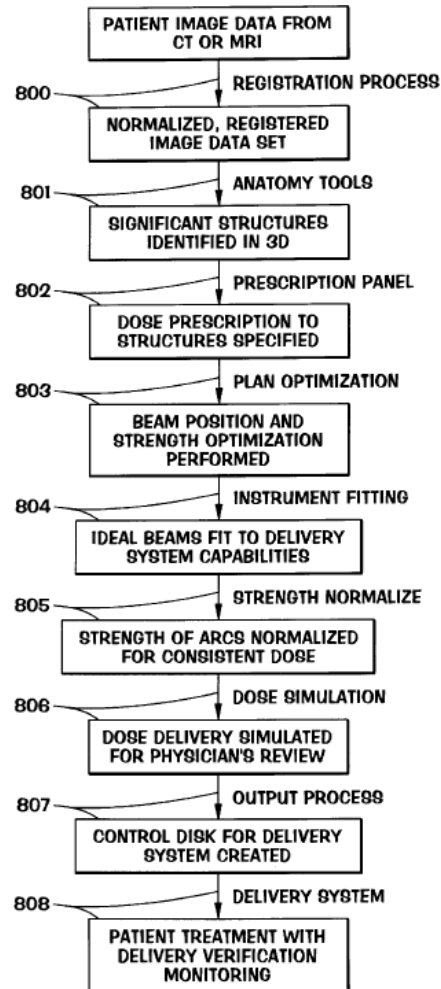
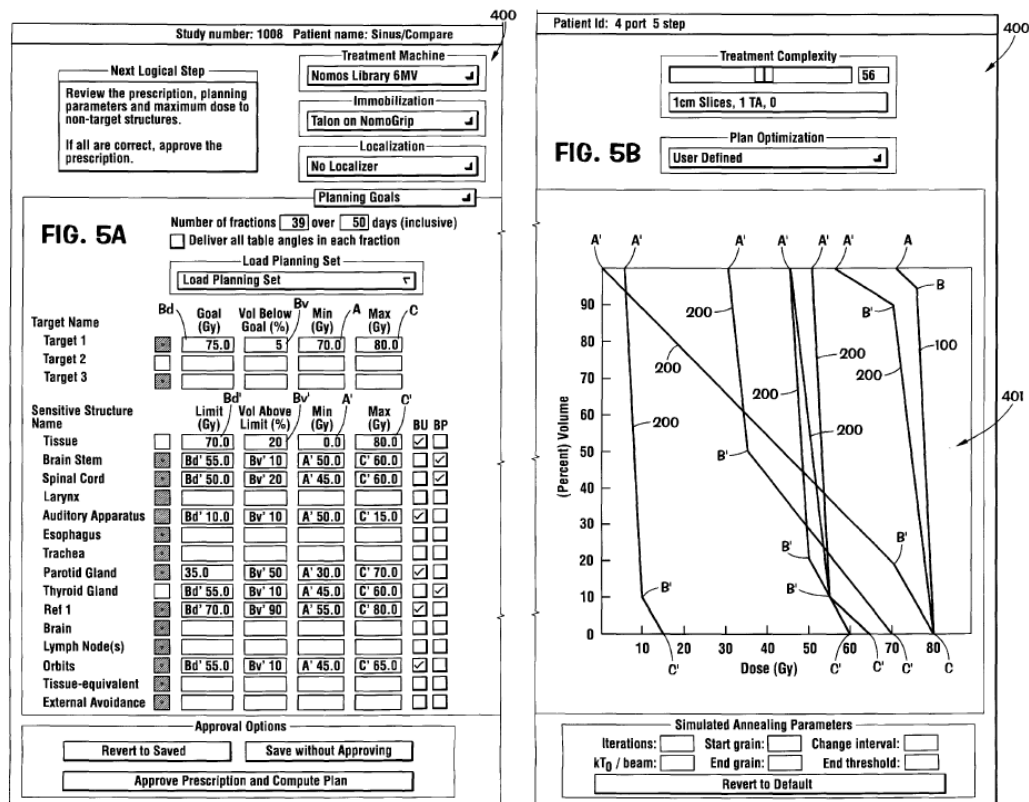


FIG. 2

The first two steps of the method, the “Registration Process” step (800) and the “Anatomy Tools” step (801) involve obtaining and identifying images of target and non-target (healthy) tissues within a patient. Col. 9, line 65-col. 10, line 30; Fig. 2.

The next step is the “Prescription Panel” step (802). Col. 10, line 31; Fig. 2. This step “allows the physician to input into the planning system the desired goal of the radiation therapy treatment, which is utilized in the plan optimization step 803.” Col. 10, lines 31-34. A “prescription panel,” such as that shown below in Fig. 5, is “used to input the [desired goal] into the planning system of the present invention.” Col. 10, lines 58-60.



“After the physician has input the desired target goals into the system according to the Prescription Panel step 802 (Fig. 2), the system of the present invention may display the corresponding target CDVH curve 100 for review by the physician.” Col. 11, lines 27-31; *see also* col. 10, lines 53-55 (“The CDVH curves 100, 200 utilized in the system of the present invention are created from partial volume data for each target and structure of a given patient.”).

The next step is the “Plan Optimization” step (803). Col. 12, line 27; Fig. 2. In the Plan Optimization step, “the radiation plan optimization is a specific case of an inverse problem, where the goal is to determine the best way to achieve the dose prescription.” Col. 12, lines 28-30. “A suitable computer is utilized in performing the Plan Optimization step, as well as the other steps of the radiation planning system.” Col. 12, lines 45-47. The ‘283 patent explains that “[a] SARP technique is utilized to do this optimization by dividing the radiation delivery into a large number of

small beams, each of which hit the target. The annealing cooling schedule utilized, fits into the class of FSA (Fast Simulated Annealing) techniques.” Col. 12, lines 30-34. The patentees explain that “[e]xcept for the foregoing detailed description of the cost function utilized in the present system, the details of the foregoing simulated annealing techniques are known in the art and are described in such publications as ‘Optimization of Conformal Radiotherapy Dose Distributions by Simulated Annealing’, S. Webb, Physics and Medical Biology, Vol. 34, PP. 1349-1370 (1989)[‘Webb (1989)’]; and ‘Optimization of Conformal Radiotherapy Dose Distributions by Simulated Annealing: 2. Inclusion of Scatter in the 2d Technique’, S. Webb, Physics and Medical Biology, vol. 36, pp. 1227-1237, (1991)[‘Webb (1991)’].” Col. 12, lines 34-44. Thus, the ‘283 patent relies on Webb (1989) and Webb (1991) for a further disclosure of SARP.

Regarding the detailed description of the “cost function,” the ‘283 patent states that “[t]he cost function is an analytical determination of whether, when any change is made to the strengths of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user.” Col. 13, lines 1-4. The patentees explain that “[i]n the cost function of the present invention, each region, or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone, of the CDVH.” Col. 13, lines 4-6. “A zone cost is then calculated for the target and each structure” based on “the weight assigned to the current zone,” “the area of the current zone of the proposed CDVH curve,” and “the area of the current zone of the desired CDVH curve.” Col. 13, lines 7-16. “After each zone cost is calculated, the target or structure cost is calculated for each target or structure.” Col. 13, lines 20-22. “The total cost for the change to the proposed beam distribution is then calculated.” Col. 13, lines 32-39. The ‘283 patent provides formulas for those calculations.

As noted above, “[b]y assigning different weights to different zones of the CDVH curves, different results can be obtained.” Col. 13, lines 53-54. According to the ‘283 patent, “[c]linical experience has shown that there are two types of structures, each category of which responds differently to radiation:” namely, “biologically polymorphic structure[s]” or “BP structures,” and “biologically uniform structure[s]” or “BU structures.” Col. 14, lines 11-13. In a BP structure, “each portion of the structure serves a distinct function: if any portion of the structure, no matter how small, is destroyed, the overall function of the structure is affected.” Col. 14, lines 18-21. “For a BP structure, zones S4, S5, and S8 may be chosen as important, with zone S8 representing the

maximum dose received by any portion of the structure being chosen as the most important zone for that type of structure.”

In contrast, in a BU structure, “all portions of the BU structure perform the same function. Overdosing one portion of the BU structure may be acceptable as long as a sufficient portion of the BU structure is preserved.” Thus, “[f]or a BU structure, where maximum dose is not important as long as the desired volume of structure falls under the chosen limit, only zone S4 may be important.” Col. 14, lines 35-38. According to the patentees, “[t]he weights can then be chosen through experience and minimal experimentation by one skilled in the art so that the * * * treatment objectives can be met in a desired application depending on the aggressiveness of the treatment plan.” Col. 15, lines 16-20.

The ‘283 patent explains that “[t]he cost function of the present invention may be easily incorporated into existing SARP algorithms by one skilled in the art.” Col. 15, lines 44-46.

The remaining steps of the planning process involve fitting “the resulting optimized set of radiation beam positions and beam weights, or beam intensities for the radiation beam segments” “into the delivery capabilities of the LINAC apparatus;” “normaliz[ing] the arcs of rotation through which the radiation beam source travels to insure that the tumor receives a consistent radiation dose from each position selected in order to eliminate what are known as ‘hot’ or ‘cold’ regions in the tissue volume being treated;” simulating “the radiation dose to the patient” “based upon the Three-Dimensional Modified Path Length technique;” “permit[ing] the physician to review the simulated radiation dose information and * * * approve the radiation plan for patient delivery;” and performing “the method steps of the conformal radiation therapy method of the present invention * * * in order to treat the tumor in the patient.” Col. 15, line 47-col. 16, line 25.

IV. Disputed Claim Terms

As noted above, Best Medical asserts independent claims 25 and 29. As discussed below, the parties have substantially narrowed the number of claim construction issues for claim 25, and have agreed on construction of claim 29. The disputed terms and issues in connection with claim 25, as well as the agreed construction for claim 29, are discussed below.

A. Claim 25

Claim 25 is reproduced below for reference:

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

1. Claim Construction Issues

During the briefing and subsequent *Markman* Hearing, the parties agreed to the construction of several terms which were initially disputed. Initially, the parties had urged the following proposed constructions for various disputed terms of claim 25:

Claim Term	Best Medical	Accuray
“An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:”	<u>Preamble:</u> The preamble is not limiting.	<u>Preamble:</u> Preamble is limiting.
	<u>apparatus:</u> “The term ‘apparatus’ does not require construction. To the extent that a construction is required, ‘apparatus’ should be construed in accordance with its plain meaning: a machine, device or system.”	

Claim Term	Best Medical	Accuray
	<p><u>An apparatus for determining an optimized radiation beam arrangement:</u> “An apparatus (machine, device or system) for determining an ‘optimized radiation beam arrangement’ (as construed below).”</p>	<p><u>An apparatus for determining an optimized radiation beam arrangement:</u> “A computer configured to use the simulated annealing (“SARP”) optimization algorithm to determine the optimal array of beam weights for the beam elements at each orientation based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm.”</p>
		<p><u>optimized radiation beam arrangement:</u> “The optimal array of beam weights for the beam elements at each orientation based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm.”</p> <p>“The beams are arranged at appropriate orientations relative to the tumor volume and divided into beam elements at each orientation.”</p> <p>“‘Optimized radiation beam arrangement’ has the same meaning throughout the claim.”</p>
<p>“a computer adapted to computationally obtain a proposed radiation beam arrangement”</p>	<p><u>computer:</u> “The term ‘computer’ does not require construction. To the extent that a construction is required, ‘computer’ should be construed in accordance with its plain meaning: a programmable electronic device that can store, retrieve, and process data.”</p>	<p><u>computer:</u> “The specific computer that performs the beam weight optimization.</p> <p>The term computer has the same meaning throughout the claim.”</p>

Claim Term	Best Medical	Accuray
	<u>adapted to computationally obtain:</u> “The ‘computer’ (as construed above) is programmed to obtain a ‘proposed radiation beam arrangement’ (as construed below).”	<u>adapted to computationally obtain:</u> “The computer is configured to run the Simulated Annealing algorithm (“SARP”) to calculate an array of proposed beam weights for the beam elements at each orientation during a given iteration of the simulated annealing (“SARP”) algorithm from partial volume data for each target and structure that is input into the computer by the user.”
	<u>radiation beam arrangement:</u> “Beam positions around a treatment field and/or an array of beam weights, intensities, or fluence profiles.”	
	<u>a proposed radiation beam arrangement:</u> “The term ‘proposed’ does not require construction in light of the construction of the phrase ‘radiation beam arrangement.’ To the extent that a construction is required, ‘proposed radiation beam arrangement’ should be construed in accordance with its plain meaning: a suggested radiation beam arrangement.”	<u>a proposed radiation beam arrangement:</u> “An array of proposed beam weights for the beam elements at each orientation calculated using the simulated annealing (“SARP”) algorithm during a given iteration of the simulated annealing (“SARP”) algorithm from the partial volume data input by the user for each target and structure. ‘Adapted to’ has the same meaning throughout the claim.”
“the computer further adapted to	<u>computer:</u> See above.	<u>computer:</u> The same computer as above.

Claim Term	Best Medical	Accuray
computationally change the proposed radiation beam arrangement iteratively”	<u>further adapted to computationally change the proposed radiation beam arrangement iteratively:</u> “The ‘computer’ (as construed above) is programmed to change the ‘proposed radiation beam arrangement iteratively’ (as construed below).”	<u>further adapted to computationally change the proposed radiation beam arrangement iteratively:</u> “Configured to run the Simulated Annealing algorithm (“SARP”) to change the proposed radiation beam arrangement by adding or subtracting beam weights to beam elements randomly at each iteration (or each cycle) of the SARP algorithm.”
	<u>change the proposed radiation beam arrangement iteratively:</u> “changing, (altering, varying or modifying) the proposed radiation beam arrangement repeatedly. The term ‘change’ does not require construction. To the extent that a construction is required, ‘change’ should be construed in accordance with its plain meaning: alter, vary or modify.”	
		<u>further adapted:</u> “running the same optimization algorithm as above (“SARP”).”
		<u>computationally change:</u> “using the simulated annealing algorithm (“SARP”) to add or subtract beam weight to the beam elements randomly.”
		<u>iteratively:</u> “in cycles of the simulated annealing (“SARP”) algorithm.”
“wherein the proposed radiation	<u>beam weights:</u> “the beam intensities or dose.”	<u>beam weights:</u> “beam intensities.”

Claim Term	Best Medical	Accuray
beam arrangement is changed by changing the beam weights”	<u>changing the beam weights:</u> “changing (altering, varying or modifying) the beam weights (the beam intensities or dose). The term ‘change’ does not require construction. To the extent that a construction is required, ‘change’ should be construed in accordance with its plain meaning: alter, vary or modify.”	<u>changing the beam weights:</u> “adding or subtracting small quanta of positive and negative beam intensities to the beam elements randomly using the simulated annealing (‘SARP’) algorithm.”
“the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription”	<u>computer:</u> See above.	
	<u>further adapted to incorporate . . .:</u> “The ‘computer’ (as construed above) is programmed to incorporate a ‘cost function’ (as construed below) at each iteration or step to approach correspondence of ‘partial volume data’ (as construed below).”	<u>further adapted to incorporate a cost function at each iteration:</u> “The computer configured to run the simulated annealing (‘SARP’) algorithm incorporates a cost function in each cycle of the SARP algorithm.”
		<u>at each iteration:</u> “at each cycle of the simulated annealing (‘SARP’) algorithm. During each iteration, beam weight is added or subtracted from beam elements, and the cost function incorporated in the simulated annealing algorithm measures the total dosage cost of the change to the proposed radiation beam arrangement, or the difference between the proposed radiation beam arrangement and the predetermined desired dose prescription.”
	<u>cost function:</u> “An analytical determination of whether, when any change is made to the strength of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user.”	<u>cost function:</u> “The cost function of the present invention is explicitly defined at col. 13, lines 4-39, including each of the steps described therein: ‘In the cost function of the present

Claim Term	Best Medical	Accuray
		<p>invention, each region, or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone, of the CDVH. A zone cost is then calculated for the target and each structure, according to the following formula: $C_z = W_z * (A_p / A_d)$,</p> <p>After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula: $C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}$, and $C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}$,</p> <p>The total cost for the change to the proposed beam distribution is then calculated, according to the following formula: $C_{Total} = C_S + C_T$, where C_{Total} is the total cost of the proposed change to the beam distribution.'</p> <p>"Partial volume data (defined below) for each target and each structure are input parameters for the cost function entered by the user for determining the proposed radiation dose distribution to a patient. The cost function measures the total dosage cost of the change to the proposed radiation beam arrangement, or the difference between the proposed radiation beam arrangement and the predetermined desired dose prescription."</p>
	<p><u>a cost function at each iteration:</u> "At each iteration or repeated step, a cost function (as construed above) is calculated."</p>	

Claim Term	Best Medical	Accuray
	<u>to approach correspondence:</u> “The phrase ‘to approach correspondence’ does not require construction. To the extent that a construction is required, ‘to approach correspondence’ should be construed in accordance with its plain meaning: to get closer to.”	<u>to approach correspondence:</u> “The cost function calculates a total dose cost for the change to the proposed radiation beam arrangement which is a metric for how close the partial volume data (or CDVH) of the proposed radiation beam arrangement of the current iteration is to the partial volume data (or CDVH) of the desired dose prescription. To approach correspondence means to minimize the difference between the proposed radiation beam arrangement and the desired dose prescription, or in other words, to minimize the total dose cost.”
	<u>partial volume data:</u> “What percentage of the volume of a tumor or structure can receive how much dose.”	<u>partial volume data:</u> See construction below.
	<u>desired dose prescription:</u> “the dosages to be achieved in the target and structure volumes.”	<u>desired dose prescription:</u> See construction below.
	<u>a pre-determined desired dose prescription:</u> “The term ‘pre-determined’ does not need to be separately construed from the phrase ‘desired dose prescription.’ To the extent that a construction is required, ‘pre-determined’ should be construed in accordance with its plain meaning: determined beforehand.”	<u>a pre-determined desired dose prescription:</u> See construction below.

Claim Term	Best Medical	Accuray
	<p><u>partial volume data associated with the proposed radiation beam arrangement:</u></p> <p>“The partial volume data (as construed above) is associated with the proposed radiation beam arrangement (as construed above). The phrase ‘associated with’ does not require construction. To the extent that a construction is required, ‘associated with’ should be construed in accordance with its plain meaning: connected or related to.”</p>	<p><u>partial volume data associated with the proposed radiation beam arrangement:</u></p> <p>“Numerical values corresponding to values represented as specific data points on CDVH curves associated with each target and each involved structure based on the proposed radiation beam arrangement, which data points define the CDVH curves and the proposed zones incorporated in the cost function; generated within a given iteration of the simulated annealing (“SARP”) algorithm.”</p>

Claim Term	Best Medical	Accuray
	<p><u>Partial volume data associated with the predetermined desired dose prescription:</u></p> <p>“The partial volume data (as construed above) is associated with the predetermined desired dose prescription (as construed above). The phrase ‘associated with’ does not require construction. To the extent that a construction is required, ‘associated with’ should be construed in accordance with its plan meaning: connected or related to.”</p>	<p><u>Partial volume data associated with the predetermined desired dose prescription:</u></p> <p>“Numerical values corresponding to values represented as specific data points on CDVH curves for each target, including at least: the minimum dose to be received by any portion of the target volume that will be underdosed [A], the desired dose to be achieved in the target volume [Bd], the portion of the target volume which should have a dose greater than the goal [Bv], and the target maximum dose value to be received by any portion of the target [C], and for each structure, including at least the desired dosage limit not to be exceeded in the volume of a sensitive structure [Bd’]; the maximum dose to be received by any portion of the structure [C’]; the dose below which there is no appreciable benefit gained by reducing the exposure to the structure [A’]; and the portion of the structure volume which can have a dose greater than the goal dosage may be represented by structure percent over limit value [Bv’]; which data points define the CDVH curves and the zone incorporated in the cost function.”</p>
<p>“the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation</p>	<p><u>computer:</u> See above</p> <p><u>further adapted to reject ...:</u> “The ‘computer’ (as construed above) is programmed to reject the ‘change of the proposed radiation beam arrangement...’ (as construed above).”</p>	<p><u>further adapted to reject...and to accept:</u> “Uses the same optimization algorithm (“SARP”).”</p>

Claim Term	Best Medical	Accuray
beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription”	<u>the change of the proposed radiation beam arrangement:</u> See above.	<u>the change of the proposed radiation beam arrangement:</u> “The new array of proposed beam weights for the beam elements at each orientation resulting from using the simulated annealing (“SARP”) algorithm to add or subtract beam weight randomly during a given iteration.”
		<u>correspondence:</u> “The cost function calculates a total dose cost for the change to the proposed radiation beam arrangement which is a metric for how close the partial volume data (or CDVH) of the proposed radiation beam arrangement of the current iteration is to the partial volume data (or CDVH) of the desired dose prescription. To approach correspondence means minimizing the difference between the proposed radiation beam arrangement and the desired dose prescription, or in other words, to minimize the total dose cost.”

Claim Term	Best Medical	Accuray
	<p><u>leads to a lesser correspondence to the desired dose prescription:</u> “The ‘proposed radiation beam arrangement’ (as construed above) would cause a dosage of radiation that is further from the ‘desired dose prescription’ (as construed above).”</p>	<p><u>leads to a lesser (greater) correspondence:</u> “Comparing the total dosage cost (the output of the cost function) of the changed proposed radiation beam arrangement from the current iteration to the total dose cost (the output of the cost function) of the proposed radiation beam arrangement from the previous iteration. If the total dosage cost of the changed proposed radiation beam arrangement of the current iteration is less than the total dosage cost of the proposed radiation beam arrangement from the previous iteration, the change to the proposed radiation beam arrangement is accepted. If the total dosage cost of the change to the proposed radiation beam arrangement from the current iteration is greater than the total dosage cost of the proposed radiation beam arrangement from the previous iteration, then the change to the proposed radiation beam arrangement is rejected.”</p>
	<p><u>leads to a greater correspondence to the desired dose prescription:</u> “The ‘proposed radiation beam arrangement’ (as construed above) would cause a dosage of radiation that is closer to the ‘desired dose prescription’ (as construed above).”</p>	

Claim Term	Best Medical	Accuray
“to obtain an optimized radiation beam arrangement.”	<u>optimized radiation beam arrangement:</u> “an arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient.”	<u>optimized radiation beam arrangement:</u> “the optimal array of beam weights for the beam elements at each orientation based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm. The beams are arranged at appropriate orientations relative to the tumor volume and divided into beam elements at each orientation.”

JCC at 1-95; Best Medical’s Brief at 4.

The parties reduced the scope of the dispute during the *Markman* Hearing. With respect to the phrases beginning with “a computer, adapted to * * *,” “the computer further adapted to * * *,” “the computer further adapted to * * *,” and “the computer further adapted to * * *,” Accuray summarized its contentions as requiring that those terms meant “a computer program[med] to perform the SARP algorithm.” *See Markman* Tr. at 138. Accuray argued that each of the functions that the recited computer was “adapted” to perform “takes place during the SARP algorithm.” *Id.* Accuray agreed that the Court could simply decide “whether or not Claim 25 is limited to the SARP algorithm * * *.” *Id.* at 140. *See also id.* at 151 (“You can look at the claim as limited to the SARP family of algorithms with the preferred embodiment being fast simulated annealing [sic]. You can look at it instead as the disclosed embodiment being SARP and perhaps a little bit broader, the stochastic algorithms, but the point really is that the kind of algorithm you use has to match the cost function and that other non-stochastic algorithms won’t work with the cost function.”).

Accuray further agreed that deciding two more issues would resolve the parties’ dispute over the scope of claim 25. Accuray asked that the Court decide whether the term “cost function” could be any cost function, or whether “cost function” meant the cost function disclosed at lines 4-39 of column 13 of the ‘283 patent. *See id.* at 141. Accuray also asked that the Court decide “what does changing the beam weight mean? Does changing the beam weight mean changing the beam weight for the beam intensity, or does changing the beam weight also include changing the beam, like adding a beam or removing a beam?” *Id.* at 142.

Best Medical expressed no disagreement that the master could resolve the parties' claim construction dispute with respect to claim 25 by addressing those three issues. Accordingly, the master addresses each of those issues in turn below.

2. Whether Claim 25 is limited to the SARP algorithm

The primary dispute between the parties concerns whether claim 25 is limited to "the SARP algorithm." See *Markman* Tr. at 69-71, 117; 137-41. As noted above, every construction urged by Accuray for claim 25 includes reference to "the SARP algorithm." See JCC at 98, 104, 112, 120, 128-29, 137.

a) The Parties' Arguments

In response to Accuray's originally proposed claim constructions, Best Medical argued that Accuray "makes the first of many attempts to improperly import limitations from the specification into the claims." Best Medical's Brief at 7. Specifically, Best Medical argued that "[t]o the extent that Accuray argues that the 'SARP algorithm' should be read into Claim 25 because SARP is described as a preferred embodiment in the specification of the '283 patent, such arguments have consistently been rejected by the Federal Circuit." *Id.* Best Medical cites to the specification of the '283 patent in urging that SARP is the preferred embodiment:

"While the invention will be described in connection with the preferred embodiment, it **will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents**, as may be included within the spirit and scope of the invention as to be defined by claims to be filed in a non-provisional application."

Id. (quoting col. 8, lines 51-57; Best Medical's emphasis).

In addition, relying on the doctrine of claim differentiation, Best Medical argues that "[t]he SARP algorithm is **not** recited in Claim 25, but, in fact, is explicitly recited in non-asserted Claims 3, 5, 15, 19, 43 and 45." *Id.* at 8 (Best Medical's emphasis). "Accordingly, Accuray's attempt to read the limitation of the 'SARP algorithm' into Claim 25 generally *** is incorrect and should be rejected." *Id.*

Accuray responds that the '283 patent specification "focuses solely on how to determine the 'optimal' **array of beam weights** using SARP, and relies heavily on the purported incorporation by reference of the Webb articles on simulated annealing to do so." Accuray's Reply at 20 (Accuray's emphasis). Additionally, Accuray urges, "[t]he specification repeatedly states that the Simulated

Annealing algorithm, referred to as ‘SARP,’ (a term coined by Dr. Webb), is used to determine an optimized beam arrangement.” *Id.* According to Accuray, the “only optimization algorithm disclosed in the specification is the simulated annealing algorithm (‘SARP’),” and “[t]he specification refers to the Fast Simulated Annealing variant (FSA) of the simulated annealing algorithm as the preferred embodiment.” *Id.* Accuray argues that “[t]he specification provides no disclosure of any optimization algorithm other than the simulated annealing algorithm, and relies on Webb for the only detailed disclosure of how SARP optimizes beam weights.” *Id.* at 20-21. “The only apparatus disclosed in the specification for determining this optimized radiation beam arrangement is a computer configured with and running plan optimization software that includes the simulated annealing algorithm. *Id.* at 21. “Although other equipment is disclosed in the specification for treatment delivery (*e.g.*, the linear accelerator and the patient couch), this equipment is not necessary for optimizing beam weights.” *Id.*

Accuray also urges that “[t]he specification treats ‘optimized’ as a relative term, dependent on the particular optimization algorithm and input parameters used.” *Id.* at 21. “The specification discloses particular input parameters and a specific cost function that are used by the simulated annealing algorithm to arrive at an optimized array of beam weights.” *Id.*

Accuray relies on the declaration of Dr. Isaac Rosen in arguing that “[a]t the time of filing, one of skill in the art would have understood, in light of the specification and his or her knowledge in the field, that the asserted claims are limited to an apparatus for determining the optimization of beam weights using the simulated annealing algorithm.” *Id.* at 22. Accuray also argues that “[a]t the time of filing, one of skill in the art would have understood * * * that the asserted claims are limited to an apparatus for determining the optimization of beam weights using the simulated annealing algorithm.” *Id.* at 22. Accuray contends that “[s]imulated annealing methods had been used for a number of years to optimize beam weights, and of the many variants of simulated annealing, including Fast Simulated Annealing. Skilled artisans knew of the advantages associated with simulated annealing, including its relative simplicity and the fact that it was ‘well-suited for complex many-dimensional cost functions.’” *Id.* (citations omitted).

Accuray also argues that “to use an optimization algorithm other than simulated annealing would have required additional experimentation,” and that the cost function disclosed in the ‘283

patent could not be used with other optimization algorithms without significant experimentation by those of skill in the art. *Id.* at 27, 41, 48.

Accuray argues that Best Medical's "constructions resurrect the outdated *Texas Digital* approach to claim construction that was expressly repudiated by the Federal Circuit in *Phillips*. Ignoring context, [Best Medical] proffers a generic construction of 'apparatus,' relying on an English language dictionary published two years after the patent issued." *Id.* at 22-23. Accuray also argues that Best Medical "reads the claim as if it were directed to an entire Treatment Planning System, or a radiation therapy system that includes both treatment planning and delivery, but to one skilled in the art, even a cursory review of the specification reveals that the '283 patent is directed to optimization of beam weights, which is just one aspect of a radiation Treatment Planning System." *Id.* at 23.

Accuray urges that "[t]he written description repeatedly characterizes 'the invention' as a narrow improvement over the art that uses a known optimization algorithm ('SARP') and a 'modified' cost function defined in the specification." *Id.* at 23. Accuray also argues that "[t]he prosecution history further supports Accuray's construction." *Id.* at 30.

Accuray repeats many of those arguments in connection with various limitations of claim 25.

In reply, Best Medical argues that "Accuray attempts to construe various claim terms of Claim 25 by improperly importing limitations from the specification of the '283 Patent and ignores the ordinary and customary meaning of the claim terms. In particular, Accuray bases its proposed construction of various terms on the preferred embodiment that are disclosed [sic] in the specification of the '283 Patent." Best Medical's Reply at 9. Best Medical argues that:

[e]xamples of Accuray's improper importation of limitations from the specification include: (1) Accuray's attempt to include Simulated Annealing Radiotherapy Planning ("SARP") as a limitation for *each and every term of Claim 25*; and (2) Accuray's attempt to include Cumulative Dose Volume Histogram ("CDVH") curves, including specific calculations not claimed in Claim 25, as limitations for the claim term '*the computer further adapted to incorporate a cost function at each iteration...to partial volume data associated with a pre-determined desired dose prescription*', and the claim term '*the computer further adapted to reject the change of the proposed radiation beam arrangement...leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement*.'

Id. at 9-10 (citations omitted, Best Medical's emphasis). Best Medical urges that "Accuray's attempted importation of limitations from the specification of the '283 Patent, including the

preferred embodiment disclosed in the specification, is contrary to current claim construction principles as set forth by the Federal Circuit.” *Id.* at 10. Best Medical argues that:

The Court in *Phillips* reaffirmed that claim terms are given their ‘ordinary and customary meaning’ as a person of ordinary skill in the art at the time of filing the patent application would understand their meaning to be. *See Phillips*, 415 F.3d at 1312-13. A claim term may be given a meaning other than its ordinary and customary meaning if the patentee specifically defines the term or intentionally disclaims or disavows claim scope. *Id.* at 1320. As the Federal Circuit made clear in *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed. Cir. 2002):

First, the claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history...Second, a claim term will not carry its ordinary meaning if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention...Third,...a claim term also will not have its ordinary meaning if the term ‘chosen by the patentee so deprive[s] the claim of clarity’ as to require resort to the other intrinsic evidence for a definite meaning...Last,...a claim term will cover nothing more than the corresponding structure or step disclosed in the specification, as well as equivalents thereto, if the patentee phrased the claim in step- or means-plus-function format.

Id. at 10-11. Best Medical argues that “Best Medical has not narrowly defined the claim terms at issue in Claim 25 and has not intentionally disclaimed or disavowed the scope of Claim 25.” *Id.* at 11. Best Medical contends that “[t]he Federal Circuit also has established that a court should not limit the scope of a claim unless the prosecution history ‘clearly’ calls for a narrow definition.” *Id.* at 11.

Best Medical argues that:

Accuray’s attempted importation of limitation is contrary to the weight of the law of the Federal Circuit. As the Court stated in *Phillips*, it has ‘repeatedly warned against confining the claims to [very specific] embodiments [of the invention]’ and that it has ‘expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.’ *See Phillips*, 415 F.3d at 1323 (citations omitted). The court further emphasized that ‘reading limitations from the specification into the claim’ is a ‘danger.’ *Id.*; *see also SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1340 (Fed. Cir. 2001) (‘one of the cardinal sins of patent law [is] reading a limitation from the written description

into the claims.’). Because Best Medical has not clearly disavowed the scope of Claim 25 and has not narrowly defined the terms at issue in the intrinsic record, Accuray’s importation of embodiments from the Specification of the ‘283 Patent into Claim 25 is improper as being a claim construction practice that is explicitly forbidden by the Federal Circuit.

Id. at 11-12.

Regarding Accuray’s “proposed construction of the term ‘optimized radiation beam arrangement,’ ” Best Medical argues that “Accuray improperly reads the limitation ‘the optimal array of beam weights for the beam elements at each orientation based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm’ into the claim term.” *Id.* at 12-13. Best Medical argues that “Accuray then reads SARP methods into the cost function described in Claim 25, despite the express statements in the specification that SARP is but one computational method known in the art for optimizing radiation treatment plans and that the present invention is distinguished over SARP * * *.” *Id.* at 13.

Best Medical again argues that “Accuray has ‘cherry-picked’ features in the patent specification relating to preferred embodiments of the invention, features in the prior art and object of the invention, and has re-written the claim to include features that fulfill the objectives of Accuray’s non-infringement case.” *Id.* at 16. Citing to *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1374 (Fed. Cir. 2008) and *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366 (Fed. Cir. 2007), Best Medical argues that “[i]n support of its construction, Accuray alleges that the prosecution history supports the contention that ‘proposed radiation beam arrangement’ means only ‘an array of proposed beam weights. Accuray’s support has been taken out of context from the prosecution history, because the applicant at the time did not make a clear and unambiguous disavowal of the scope of the term ‘proposed radiation beam arrangement.’ ” *Id.* at 16-17.

In addition, Best Medical argues that Accuray “attempts to incorporate the SARP algorithm into the claim scope by citing to the specification and thus ignoring the ordinary and customary meaning of the term at issue.” *Id.* at 18. In addition, in response to Accuray’s arguments that the prosecution history supports Accuray’s construction, Best Medical urges:

In the prosecution history, the Examiner rejected the claims under 35 U.S.C. § 102(e) as being anticipated by Leber et al. Even though Leber describes a type of computation algorithm called a ‘Dynamically Penalized Likelihood (DPL) iterative algorithm,’ the Examiner maintained that such an algorithm met the features recited in Claim 25. According to the Examiner:

Leber shows all of the features of the instant invention including radiation (therapy) beam optimization to a target volume and minimizing radiation to a structure volume, using a computer to modify the beam arrangement, and rejecting the new arrangement if it has a lesser correspondence to the desired radiation prescription.

(Doc. No. 131-2 at page 4 of 5). Thus, the Examiner determined that Claim 25 *was not limited to simulated annealing algorithm (SARP)*, as Accuray argues.

Id. at 18 (Best Medical’s emphasis). Best Medical contends that, in responding to the above-referenced office action, “the applicant did not restrict the recited ‘computation’ feature of SARP. In the arguments accompanying the Amendment, the applicant described the Leber reference as using the ‘Dynamically Penalized Likelihood (DPL) iterative algorithm,’ but did not argue that Claim 25 distinguished over the reference on that basis. Accuray is trying to mislead the Court by implying that this was a disclaimer.” *Id.* at 18-19. Best Medical argues that “no amendment was made to Claim 25 to add SARP, and no argument was made that SARP was the reason Claim 25 distinguished the claim over the prior art. Therefore, the Examiner, when reviewing Claim 25 for patentability, did not associate Claim 25 with the simulated annealing algorithm (SARP), and the applicant did not make a clear disclaimer of such.” *Id.* at 19.

Best Medical urges that “to create a case for non-infringement, Accuray cites extrinsic evidence from Drs. Rosen and Carol, contrary to the ordinary meaning of the claim limitation.” *Id.* Best Medical argues that “Best Medical’s construction, which is consistent with the claim language itself and the intrinsic record, should be adopted as the only construction that is true to the claim language.” *Id.* Best Medical repeats many of its arguments in connection with various claim limitations that Best Medical contends are not limited to the SARP algorithm.

Accuray replies that the terms “optimized radiation beam arrangement,” “proposed radiation beam arrangement,” “further adapted to computationally change * * *,” and “each iteration” are limited to SARP, reurging much of its arguments above. Accuray urges that Best Medical fails to respond to its “arguments that the patent’s characterization of the invention limits the claims to the disclosed embodiment,” and that ‘optimized’ is a relative term.” Accuray’s Sur-Reply at 21, 24. Accuray argues that:

[Best Medical] seems to be saying (all at the same time) that (1) SARP is excluded from the invention, (2) SARP can be part of the invention, (3) other ‘computation methods’ are distinguished and excluded from the invention, and (4) claim differentiation means that the asserted claims cannot cover SARP.

Following [Best Medical's] convoluted thinking, if SARP is not part of the invention, and other 'computation methods' are not part of the invention, what is the invention? SARP is the only optimization algorithm disclosed in the specification. No other optimization algorithm is disclosed or even mentioned, and if [Best Medical] is suggesting that claim 25 covers another undisclosed optimization algorithm, it runs straight into invalidity for lack of written description and lack of enablement. In addition, a construction that excludes the preferred (or only) embodiment is rarely if ever correct. [Best Medical] confirms with every argument it makes that it does not understand its own patent and has no basis for its infringement suit against Accuray.

Id. at 26 (citations omitted).

Regarding Best Medical's citation to *Computer Docking* and *Elbex Video*, Accuray argues that:

[Best Medical] cites to *Computer Docking* and *Elbex* to support its position, but the doctrine of prosecution disclaimer is typically used to determine whether arguments made by the applicant during prosecution to distinguish the invention over the prior art disclaim subject matter. Here, the applicant simply acquiesced in the Examiner's rejection and amended the claims as directed. Amending the claims as directed by the Examiner is a clear surrender of the subject matter. Construing the claim broadly in the face of the prosecution history can only lead to invalidation over Leber and over prior art references.

Id. at 32 (citations omitted).

Accuray also argues that "[a]s discussed in Accuray's Responsive Brief at p. 15, ordinary and customary meaning is determined from the perspective of one of skill in the art in light of the specification, and thus Accuray's claim construction, and inclusion of the SARP algorithm, is appropriate." *Id.* at 32-33.

Regarding the prosecution history of the '283 patent, Accuray argues:

[Best Medical] argues that '[e]ven though Leber describes a type of computation algorithm called a 'Dynamically Penalized Likelihood['] (DPL) iterative algorithm, the Examiner maintained that such an algorithm met the features recited in Claim 25. (Doc. No. 142 at p. 18)[.] [Best Medical] misinterprets and mischaracterizes the prosecution history. The applicant mistakenly described Leber: 'U.S. Patent No. 5,602,892, to Leber et al.' and as disclosing '[t]he preferred method and apparatus for solving the numerical optimization problem comprises a computer running a new Dynamically Penalized Likelihood (DPL) iterative algorithm (Col. 3:59-67-4:1).' See Doc. No. 131, Ex. 3 at 6-7. A search of Leber, however, reveals that that the DPL algorithm is not disclosed anywhere in the specification, but rather was disclosed in Llacer, the other prior art reference cited in the Office Action. See *id.* Indeed, the applicant had the correct patent number, but the wrong inventor name. The applicant was actually describing

Llacer, USPN 5,602,892, not Leber, USPN 5,513,238. *See* Doc. No. 131, Ex. 2 at p. 3.

In contrast, the Leber specification plainly discloses the use of simulated annealing at column 4, lines 30-36: ‘As an illustration of the way that these parameters can be used to automatically compute a dose plan in a computer workstation, we could take the process of so called simulated annealing to optimize a plan based on criteria or predetermined parameters selected by the dose planner related to these involvement, coverage, beam arc, inhomogeneity or other specifications of the plan.’ [Best Medical’s] conclusion, ‘that the Examiner determined that Claim 25 was not limited to simulated annealing algorithm (SARP)’ completely falls apart under closer scrutiny of the prosecution history.

Id. at 33.

b) Discussion

(1) The Respective Roles of the Claims and Specification

As is evident from the foregoing, one of the parties’ principal disputes concerns the proper role played by the specification in construing claims. That, in fact, is a topic that has drawn some current disagreement among Federal Circuit judges.

(a) The Role of the Claims

The Federal Circuit has consistently advised that the claim construction analysis begins with the language of the claims. *See Markman*, 52 F.3d at 980 (“The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.”). The Federal Circuit *en banc* in *Phillips*, 415 F.3d at 1312, explained that “[i]t is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’ * * * [and quoting cases] (‘we look to the words of the claims themselves * * * to define the scope of the patented invention’); * * * (‘The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.’). That principle has been recognized since at least 1836, when Congress first required that the specification include a portion in which the inventor ‘shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery.’ * * * In the following years, the Supreme Court made clear that the claims are ‘of primary importance, in the effort to ascertain precisely what it is that is patented.’ * * * Because the patentee is required to ‘define precisely what his invention is,’ the Court explained, it is ‘unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.’ * * * (‘the

claims measure the invention’); * * * (‘if we once begin to include elements not mentioned in the claim, in order to limit such claim * * *, we should never know where to stop’); * * * (‘the claims made in the patent are the sole measure of the grant’).’

The Federal Circuit, moreover, recently reiterated that “[c]laim terms are generally given their ordinary meaning as understood by persons skilled in the art in question at the time of the invention. * * * The plain meaning of claim language ordinarily controls unless the patentee acts as his own lexicographer and provides a special definition for a particular claim term or the patentee disavows the ordinary scope of a claim term either in the specification or during prosecution.” *Interdigital Communications, LLC v. U.S. Int’l Trade Comm’n*, No. 2010-1093, slip op. at 10 (Fed. Cir. August 1, 2012). *See also Phillips*, 415 F.3d at 1312-13 (“We have frequently stated that the words of a claim ‘are generally given their ordinary and customary meaning.’ * * * We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.”).

(b) The Role of the Specification

The claims, of course, appear at the end of the patent specification. In *Phillips*, the Federal Circuit explained the relationship between the specification and the claims, observing that 35 U.S.C. § 112(1) provides that the specification

shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains * * * to make and use the same * * * .

On the other hand, the Federal Circuit observed, 35 U.S.C. § 112(2) provides that the specification

shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

415 F.3d at 1311-12. The Federal Circuit explained that “[t]hose two paragraphs of section 112 frame the issue of claim interpretation for us. The second paragraph requires us to look to the language of the claims to determine what ‘the applicant regards as his invention.’ On the other hand, the first paragraph requires that the specification describe the invention set forth in the claims. The principal question that this case presents to us is the extent to which we should resort to and rely on a patent’s specification in seeking to ascertain the proper scope of its claims.” 415 F.3d at 1312.

The parties' arguments frame the same question here – namely the extent to which one may rely on the specification in seeking the proper claim construction. At one side stands the rule that claims must be interpreted “in light of” the specification. At the other side stands the rule that it is improper to import limitations from the specification into the claims. Those “rules” are not simply axioms invoked, one or the other, to justify a result, but rather serve to protect the interests of both (1) the public, and (2) the patentee. The rule that claims must be interpreted in light of the specification serves to protect the public in that it precludes a patentee from using terms and phrases to mean one thing in the specification (or during prosecution), and then urging a different meaning during litigation. The rule that it is improper to import limitations from the specification into the claims serves to protect the patentee from assertions during litigation by accused infringers that the asserted claims are actually narrower than what the express language may suggest.

(c) Express Language of Claim 25

Claim 25, once again, calls for:

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

The question, once again, is whether claim 25 is limited to “the SARP algorithm.” The parties do not dispute the meaning of the words and phrases used in the claim – only whether the claim is

limited to the SARP algorithm. It is clear, however, that the express language of the claim does not refer to “the SARP algorithm” or “simulated annealing,” or otherwise limit the claim to SARP.

(d) Accuray’s Contentions

Nevertheless, Accuray contends that “ ‘[a]pparatus for determining an optimized radiation beam arrangement’ means ‘a computer configured to use the simulated annealing (“SARP”) optimization algorithm to determine the optimal array of beam weights for the beam elements at each orientation based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm.’ ” Accuray’s Response [Dkt. No. 138] at 18-19. Accuray similarly urges that “ ‘[o]ptimized radiation beam arrangement’ means ‘the optimal array of beam weights for the beam elements at each orientation based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm.’ ” *Id.* at 19.

Accuray urges similar constructions for the other language in the claim. For example, Accuray contends:

- In the limitation “a computer, adapted to computationally obtain a proposed radiation beam arrangement” the phrase “a computer” means “the specific computer that performs the beam weight optimization,” the phrase “adapted to computationally obtain” means “configured to run the Simulated Annealing algorithm (“SARP”) to calculate ‘a proposed radiation beam arrangement,’ ” and the phrase “a proposed radiation beam arrangement” means “an array of proposed beam weights for the beam elements at each orientation calculated using the simulated annealing (“SARP”) algorithm during a given iteration of the simulated annealing (“SARP”) algorithm from the partial volume data input by the user for each target and structure.” Accuray’s Response at 23-24.
- In the limitation “the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights” the phrase “further adapted to computationally change the proposed radiation beam arrangement iteratively” means “configured to run the Simulated Annealing algorithm (“SARP”) to change ‘the proposed radiation beam arrangement’ (defined above) by adding or subtracting beam weights to beam elements randomly at each iteration (or each cycle) of the SARP algorithm.” Accuray’s Response at 29.
- In the limitation “the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription” the phrase “further adapted to incorporate a cost function at each iteration” means “the computer configured to run the simulated annealing (“SARP”) algorithm incorporates a ‘cost function’ in each cycle

of the SARP algorithm,” “At each iteration” means “at each cycle of the simulated annealing (“SARP”) algorithm,” and “cost function” means the cost function defined at column 13, lines 4-39. Accuray’s Response at 33.

- In the limitation “the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement” the phrase “the computer further adapted to reject ... and to accept ...” means the same computer uses the same simulated annealing optimization algorithm (“SARP”), and the phrase “the change of the proposed radiation beam arrangement” means “the new array of proposed beam weights for the beam elements at each orientation resulting from using the simulated annealing (“SARP”) algorithm to add or subtract beam weight randomly during a given iteration.” Accuray’s Response at 45.

Thus, Accuray contends that the claim preamble and every limitation in the body of the claim is limited to using the simulated annealing (“SARP”) algorithm, even though the express language of the claim does not so provide. Moreover, as discussed above, and as developed during the *Markman* Hearing, the parties do not dispute the meaning of the express claim language. For example, the parties do not dispute what the limitation “a computer, adapted to computationally obtain a proposed radiation beam arrangement” means – other than that Accuray contends that limitation (and the other limitations) should be construed as additionally limited to using the simulated annealing (“SARP”) algorithm, while Best Medical contends that the claims should not be so limited.

Accuray argues, *inter alia*, that although claim 25 is not, by its express terms, limited to “the SARP algorithm” or “simulated annealing,” or otherwise limited to SARP, the specification requires interpreting claim 25 as being so limited. Accuray argues, for example, in connection with the claim preamble:

- “The specification uses the term ‘optimized radiation beam arrangement’ consistently to mean ‘the optimal array of beam weights.’ ”
- “The specification discloses that the ‘optimized beam arrangement’ should be understood to include either the optimal beam arrangements around the treatment field, the optimal array of beam weights, or beam intensities, otherwise known as an intensity map or a fluence profile or both.”
- “The specification, however, provides no disclosure of how to achieve ‘the optimal beam arrangements around the treatment field,’ commonly referred to by those of skill in the art as the beam geometry or orientation.”

- “The only reference to beams is found at col. 12:27-32 (‘A SARP technique is utilized to do this optimization by dividing the radiation delivery into a large number of small beams, each of which hit the target.’)”
- “Similarly, the Webb papers provide no disclosure of optimizing beam orientation or beam geometry, but rather focus exclusively on the optimization of beam weights using the simulated annealing algorithm.”
- “The specification focuses solely on how to determine the ‘optimal’ array of beam weights using SARP, and relies heavily on the purported incorporation by reference of the Webb articles on simulated annealing to do so.”
- “The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose.”
- “The specification repeatedly states that the Simulated Annealing algorithm, referred to as ‘SARP,’ (a term coined by Dr. Webb), is used to determine an optimized beam arrangement.”
- “The only optimization algorithm disclosed in the specification is the simulated annealing algorithm (‘SARP’). In fact, the specification uses the words ‘simulated annealing’ at least twenty times and ‘SARP’ at least six times.”
- “The specification refers to the Fast Simulated Annealing variant (FSA) of the simulated annealing algorithm as the preferred embodiment.”
- “The specification provides no disclosure of any optimization algorithm other than the simulated annealing algorithm, and relies on Webb for the only detailed disclosure of how SARP optimizes beam weights.”
- “The specification further treats ‘optimized’ as a relative term, dependent on the particular optimization algorithm and input parameters used.”
- “The specification discloses particular input parameters and a specific cost function that are used by the simulated annealing algorithm to arrive at an optimized array of beam weights.”
- “The specification confirms by its consistent use of the term ‘optimal radiation beam arrangement’ to mean an ‘array of beam weights based on the treatment objectives as expressed in the cost function incorporated in the SARP algorithm’ that the claim term should be so limited.”
- “The only apparatus disclosed in the specification for determining this optimized radiation beam arrangement is a computer configured with and running plan optimization software that includes the simulated annealing algorithm.”
- “Although other equipment is disclosed in the specification for treatment delivery (e.g., the linear accelerator and the patient couch), this equipment is not necessary for optimizing beam weights.”

- “The prosecution history is in accord. The Examiner required the applicant to amend the claims to include ‘changing the beam weights’ limitation in every claim, consistent with the understanding that the optimized radiation beam arrangement is an array of beam weights, and does not include beam geometry or orientation.”

Accuray’s Response at 19-22 (Accuray’s emphases omitted).

In a nutshell, Accuray argues that claim 25 should be limited to using the simulated annealing (“SARP”) algorithm because the specification discloses only the SARP algorithm for implementing the invention. Best Medical, in response, urges that Accuray’s contention is a clear instance of improperly reading limitations from the specification into the claims.

(e) *Phillips*

As noted above, the Federal Circuit in *Phillips en banc* addressed the role of the specification in construing the claims. Nevertheless, there is currently some disagreement among Federal Circuit judges on that question. As discussed further below, some Federal Circuit judges have expressed the view that recent Federal Circuit panel opinions have interpreted the role the specification plays in claim interpretation contrary to the *en banc* opinion in *Phillips*.

The Federal Circuit in *Phillips* held *en banc*:

- the words of a claim “are generally given their ordinary and customary meaning.” 415 F.3d at 1312.
- “the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention * * *” *Id.* at 1313.
- “the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.*
- “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314.
- “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” namely the context in which a term is used. *Id.*
- “Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term. * * * Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Id.*

- “Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. * * * For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15.
- “The claims, of course, do not stand alone. Rather, they are part of ‘a fully integrated written instrument,’ * * * consisting principally of a specification that concludes with the claims. For that reason, claims ‘must be read in view of the specification, of which they are a part.’ * * * [T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* at 1315.
- “Consistent with that general principle, our cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs. * * * In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor’s intention, as expressed in the specification, is regarded as dispositive.” *Id.* at 1316.

The *en banc* Federal Circuit in *Phillips* further addressed its prior opinion in *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002), and cases adopting the *Texas Digital* rationale. The Federal Circuit in *Texas Digital* had reasoned that a court may guard against improperly importing limitations from the specification into the claims by first construing disputed claim terms to determine their ordinary and customary meaning by using, *inter alia*, dictionaries, treatises and other sources. In *Texas Digital*, the Federal Circuit wrote: “[c]onsulting the written description and prosecution history as a threshold step in the claim construction process, before any effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitations into the claims.” 308 F.3d at 1204.

In *Phillips*, the Federal Circuit *en banc* clearly discredited that approach. The Federal Circuit in *Phillips* explained that the *Texas Digital* court had “advanced the methodology set forth in that opinion in an effort to combat what this court has termed ‘one of the cardinal sins of patent law--reading a limitation from the written description into the claims,’ * * *.” 415 F.3d at 1319-20. The Federal Circuit reasoned that was not the correct approach because it elevated extrinsic materials such as dictionaries and the like over the specification: “Although the concern expressed by the court in *Texas Digital* was valid, the methodology it adopted placed too much reliance on extrinsic sources such as dictionaries, treatises, and encyclopedias and too little on intrinsic sources, in particular the specification and prosecution history. While the court [in *Texas Digital*] noted that the

specification must be consulted in every case, it suggested a methodology for claim interpretation in which the specification should be consulted only after a determination is made, whether based on a dictionary, treatise, or other source, as to the ordinary meaning or meanings of the claim term in dispute.” *Id.* at 1320.

The Federal Circuit in *Phillips* further explained that “[t]he main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. Properly viewed, the ‘ordinary meaning’ of a claim term is its meaning to the ordinary artisan after reading the entire patent. Yet heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification.” *Id.* at 1321.

On the other hand, the Federal Circuit in *Phillips* further explained that “[w]e also acknowledge that the purpose underlying the *Texas Digital* line of cases—to avoid the danger of reading limitations from the specification into the claim—is sound. Moreover, we recognize that the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice.” *Id.* at 1323.

In *Phillips*, the Federal Circuit advised that “the line between construing terms and importing limitations can be discerned with reasonable certainty and predictability if the court’s focus remains on understanding how a person of ordinary skill in the art would understand the claim terms.” *Id.* at 1323.

To explain the impropriety of reading limitations from the specification into the claims, the Federal Circuit pointed to when the specification described specific embodiments of the invention. The Federal Circuit reiterated that “although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments. * * * In particular, we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.” *Id.*

The Federal Circuit explained that the underlying rationale for not limiting claims to a specific disclosed embodiment, even if it is the only disclosed embodiment, was “not just because

section 112 of the Patent Act requires that the claims themselves set forth the limits of the patent grant,” but further “because persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments.” *Id.*

The Federal Circuit further explained that “[t]o avoid importing limitations from the specification into the claims, it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. * * * One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case.” *Id.*

The court, noting that it was improper to either (1) limit the claims to the embodiments disclosed in the specification or (2) divorce the claim language from the specification, acknowledged that “[i]n the end, there will still remain some cases in which it will be hard to determine whether a person of skill in the art would understand the embodiments to define the outer limits of the claim term or merely to be exemplary in nature.” *Id.* However, the Federal Circuit reasoned that such was preferable to improperly limiting claims to embodiments disclosed in the specification or divorcing claim language from the specification: “While that task may present difficulties in some cases, we nonetheless believe that attempting to resolve that problem in the context of the particular patent is likely to capture the scope of the actual invention more accurately than either strictly limiting the scope of the claims to the embodiments disclosed in the specification or divorcing the claim language from the specification.” *Id.* at 1323-24.

In *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996), the Federal Circuit advised *vis-à-vis* claim construction:

- “First, we look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention. * * * Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.” 90 F.3d at 1582
- “Thus, second, it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning. The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.” *Id.*

- “Third, the court may also consider the prosecution history of the patent, if in evidence.” *Id.*

In *Phillips*, the Federal Circuit *en banc* explained that “[i]n *Vitronics*, this court grappled with the same problem and set forth guidelines for reaching the correct claim construction and not imposing improper limitations on claims. * * * The underlying goal of our decision in *Vitronics* was to increase the likelihood that a court will comprehend how a person of ordinary skill in the art would understand the claim terms.” 415 F.3d at 1324. The Federal Circuit added that “there is no magic formula or catechism for conducting claim construction. Nor is the court barred from considering any particular sources or required to analyze sources in any specific sequence, as long as those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence. * * * For example, a judge who encounters a claim term while reading a patent might consult a general purpose or specialized dictionary to begin to understand the meaning of the term, before reviewing the remainder of the patent to determine how the patentee has used the term. The sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law.” *Id.* The Federal Circuit in *Phillips en banc* reaffirmed the approach to claim construction expressed in *Vitronics*. *Id.*

The reason for the extended discussion of *Phillips* is that portions of the *Phillips* opinion are frequently cited, many times out of context, to support various arguments. For example, those urging a broader claim construction (typically the patentee) frequently focus on those portions of the *Phillips* opinion that emphasize the importance of the claims, and those portions that reiterate that it is improper to import limitations from the specification into the claims. On the other hand, those urging a narrower claim construction (typically the accused infringer), frequently focus on those portions of *Phillips* that emphasize that claims are read in conjunction with the specification and are not divorced from the specification, and that emphasize the importance of the specification in construing the claims. As the Federal Circuit made clear, however, neither approach is correct in isolation from the other.

(f) Reading Limitations From the Specification Into the Claims

That it is improper to import or read limitations from the specification into the claims is a rule having a long pedigree. In *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107 (Fed. Cir.

1985)(*en banc*), for example, the Federal Circuit *en banc* explained that “[w]hen claim construction is required, claims are construable, as above indicated, in light of the specification, * * * yet ‘that claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims.’” 775 F.2d at 1121. The Federal Circuit further explained that “[i]f everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims. Nor could an applicant, regardless of the prior art, claim more broadly than that embodiment. Nor would a basis remain for the statutory necessity that an applicant conclude his specification with ‘claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.’ * * * It is the claims that measure the invention.” *Id.*

That rationale has been carried forward through and including the Federal Circuit’s *en banc* decision in *Phillips*. As noted above, those urging a narrower claim construction (typically the accused infringers in patent infringement litigation), frequently focus on those portions of *Phillips* that emphasize that claims are read in conjunction with the specification and are not divorced from the specification, and emphasize the importance of the specification in construing the claims.

However, the Federal Circuit in *Phillips* did not stray from the long-standing distinction, extending back to the Patent Act of 1836 first requiring “claims,” between (1) reading claims light of the specification, which is proper, versus (2) reading limitations from the specification into the claims, which is not.

The limited right to exclude others from practicing the invention granted by 35 U.S.C. § 271 is limited to the “patented invention,” namely the claimed invention. It has long been recognized that the *quid pro quo* for that limited grant is disclosure of the claimed invention in sufficient detail to enable one skilled in the art to practice the invention after the patent has expired. *See e.g., Universal Oil Products Co. v. Globe Oil & Refining Co.*, 322 U.S. 471, 484 (1944).

The statute enforces the disclosure requirement through 35 U.S.C. § 112(1) providing:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010)(*en banc*), the Federal Circuit concluded that “§ 112, first paragraph, contains two separate description requirements: a ‘written description [i] of the invention, and [ii] of the manner and process of making and using [the invention].’” 598 F.3d at 1344 (court’s emphasis omitted).

The Federal Circuit in *Ariad* also explained the relationship of claims to the written description requirement: “A separate written description requirement also does not conflict with the function of the claims. * * * Claims define the subject matter that, after examination, has been found to meet the statutory requirements for a patent. * * * Their principal function, therefore, is to provide notice of the boundaries of the right to exclude and to define limits; it is not to describe the invention, although their original language contributes to the description and in certain cases satisfies it. Claims define and circumscribe, the written description discloses and teaches.” 598 F.3d at 1347.

(g) The Extent To Which The Specification Can Properly Be Used In Construing Claims

The question then becomes the extent to which the specification may be used to construe the claims.

In particular, Accuray relies on the Federal Circuit panel majority opinion in *Retractable Technologies, Inc. v. Becton Dickinson and Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011), stating “[i]n reviewing the intrinsic record to construe the claims, we strive to capture the scope of the actual invention, rather than strictly limit the scope of the claims to disclosed embodiments or allow the claim language to become divorced from what the specification conveys is the invention.” Accuray’s Response at 15. Accuray also relies on Judge Plager’s concurring opinion stating:

I understand how a perfectly competent trial judge can be persuaded by the siren song of litigation counsel to give the jury wide scope regarding what is claimed. But it is a song to which courts should turn a deaf ear if patents are to serve the purposes for which they exist, including the obligation to make full disclosure of what is actually invented, and to claim that and nothing more.

Id., quoting *Retractable Techs.*, 653 F.3d at 1311 (Plager, J. concurring).

In *Retractable Techs.*, the patent-in-suit was drawn to retractable syringes, namely medical syringes that included a needle that retracted into the syringe body after the syringe was used. Two of the disputed claim terms were “retainer member” and “body.” The question *vis-à-vis* “retainer member” was whether that required two separate parts. The Federal Circuit agreed with the district

court that the term did not require two separable parts. The Federal Circuit noted that “[t]he specifications also indicate that the ‘needle holder’ and the ‘retainer member’ need not be separately molded pieces.” 653 F.3d at 1303. Thus, the Federal Circuit gave “retainer member” its ordinary meaning which did not require two separate parts, and used the specification to confirm that the patentee had not said something different in the specification, for example by “defining” “retainer member” as meaning one made from two separate parts, or by requiring “retainer members,” in the context of the invention, to have two separate parts.

The question *vis-à-vis* “body” was similar, *i.e.*, whether the “body” was required to have a one-piece construction. Here, the panel majority in an opinion by Judge Lourie, over a dissent by Chief Judge Rader, concluded that “[t]he specifications indicate that the claimed ‘body’ refers to a one-piece body. In distinguishing prior art syringes comprised of multiple pieces, the specifications state that the prior art had failed to recognize a retractable syringe that ‘can be molded as one piece outer body.’ *** Consistent with this characterization of the prior art, the Summary of the Invention states that ‘[t]he invention is a retractable tamperproof syringe,’ and that this syringe ‘features a one piece hollow body.’” 653 F.3d at 1305. The panel majority also noted that “the specifications, in describing the invention, expressly state that each syringe embodiment contains a one-piece body.” *Id.*

Chief Judge Rader read the patent differently. Chief Judge Rader, emphasizing that in *Phillips*, “this court recognized as ‘a bedrock principle of patent law’ that the claims themselves, not the written description portion of the specification, define the patented invention,” concluded that “[t]he ordinary and customary meaning of ‘body’ does not inherently contain a one-piece structural limitation. Moreover, neither the claim language nor the written description evinces intent by the patentee to limit the scope of ‘body’ to one-piece bodies.” 653 F.3d at 1312 (Rader, CJ, dissenting-in-part).

The rule against importing limitations from the specification into the claims, or limiting the claims to the disclosed embodiment(s), even if there is only one embodiment, simply recognizes that a patentee may choose to use claims of varying scope to protect what the patentee regards as his invention. After all, 35 U.S.C. § 112(2) provides that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” (emphasis added).

It is the applicant's prerogative how best to claim what he regards as his invention. And while it is perfectly proper to construe claim terms, it is improper to rewrite the claims. *See e.g., Retractable Techs. v. Becton, Dickinson & Co.*, 659 F.3d 1369, 1372 (Fed. Cir. 2011)(Moore, J., dissenting from denial of rehearing *en banc*) (“The error in *Retractable* is the majority’s attempt to rewrite the claims to better conform to what it discerns is the ‘invention’ of the patent instead of construing the language of the claim. * * * Regardless of what ‘the inventor actually invented,’ it is clear that the only construction of the term ‘body’ that comports with the patent as a whole, as well as the plain meaning of the term, includes both single and multi-piece bodies.”). *See also, IGT v. Bally Gaming Int’l, Inc.*, 659 F.3d 1109, 1117 (Fed. Cir. 2011); *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 396 (Ct. Cl. 1967)(“Courts can neither broaden nor narrow the claims to give the patentee something different than what he has set forth. No matter how great the temptations of fairness or policy making, courts do not rework claims. They only interpret them.”).

Patentees may choose to write claims that are not limited to specific embodiments described in the specification. After all, an applicant is required to disclose an embodiment of the invention – not necessarily all embodiments of the invention. During prosecution, such claims are examined for compliance with the novelty and non-obviousness statutory requirements, 35 U.S.C. §§ 102, 103, as well as for compliance with the disclosure, 35 U.S.C. § 112(1), and precision in claiming, 35 U.S.C. § 112(2), requirements. Once issued in a patent, such claims are entitled to the statutory presumption of validity under 35 U.S.C. § 282.

It may turn out that later in litigation there is a question whether the scope of the written description and enablement portions of the specification are commensurate with the scope of the claims. In *MagSil Corp. v. Hitachi Global Storage Technologies, Inc.*, No. 2011-1221 (Fed. Cir. August 14, 2012), for example, the patentee urged a broad claim construction which the district court had adopted. Subsequently, however, the district court found on summary judgment that the claim, having the breadth that the patentee urged, was invalid because of a failure to provide an enabling disclosure commensurate in scope with the claim. The Federal Circuit concluded: “The record shows that MagSil advocated for a broad construction of this claim term. Its expert Dr. Murdock testified that this term covers tunnel junctions with resistive changes of 100% or more. * * * The specification—the disclosure available to show the full scope of enablement—teaches that the inventors’ best efforts achieved a maximum change in resistance of only 11.8% at room temperature. * * * Hitachi has shown with clear and convincing evidence that one skilled in the art

could not have taken the disclosure in the specification regarding ‘change in the resistance by at least 10% at room temperature’ and achieved a change in resistance in the full scope of that term without undue experimentation.” Slip op. at 8. The Federal Circuit noted that “a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.” *Id.*, at 6-7. *See also, Liebel-Flarsheim Co. v. Medrad, Inc. (Liebel II)*, 481 F.3d 1371, 1380 (Fed. Cir. 2007) (“The irony of this situation is that Liebel successfully pressed to have its claims include a jacketless system, but, having won that battle, it then had to show that such a claim was fully enabled, a challenge it could not meet.”).

There is no question that the written description and enablement requirements of § 112(1) impose restrictions on the scope of claims under the penalty of invalidity. Once again, the disclosures mandated by § 112(1) constitute the *quid pro quo* for the limited exclusive rights bounded by the claims.

In *Retractable Techs.*, though, Judge Lourie wrote that “we strive to capture the scope of the actual invention * * *.” In addition to Judge Moore’s comment above, in dissenting from a denial of rehearing *en banc*, that such an analysis substitutes the court’s view of the “actual invention” for the inventor’s view of the “actual invention” under § 112(2), if taken as a general rule, the focus for determining the “actual invention” shifts from the claims, which all agree measure the scope of exclusionary rights granted under § 271, to a more subjective search for the “actual” invention.

There may be instances where a specification clearly “defines” an invention such that using the written description in an effort to define claim scope falls within the category of “reading claims in light of the specification” as opposed to “reading limitations from the specification into the claims.” Judge Lourie viewed the specification at issue in *Retractable* as such a specification which, in his view, supported limiting the otherwise broad claim term “body” to a “one-piece body.” But, as also noted above, Chief Judge Rader read the specification differently, and concluded that the reference to a “one-piece” body was simply a disclosed embodiment. Judge Moore reached the same conclusion.

In all events, it is the province of the claims to set out what constitutes (1) subject matter that the PTO has determined meets the requirements for patentability, and (2) “subject matter which the applicant regards as his invention.” In *Retractable*, Chief Judge Rader’s analysis would have given the term “body” in the claims its ordinary meaning which, of course, is not limited to a “one-piece”

construction. It may – or may not – ultimately turn out that giving “body” its ordinary meaning would result in a conclusion that such claim was invalid for lack of a commensurate enabling disclosure, as in *MagSil*. But questions of enablement involve a different set of questions, and a different standard of proof.

For example, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without “undue experimentation.” What constitutes “undue experimentation” depends on a number of factors. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)(“Factors to be considered in determining whether a disclosure would require undue experimentation * * * include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” (sentences combined by ellipses)). Also, a party must prove invalidity based on non-enablement by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011).

In *Arlington Indus. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246 (Fed. Cir. 2011), mentioned by Judge Plager in his concurring opinion in *Retractable Techs.*, Judge Lourie and Chief Judge Rader again appeared on opposite sides of the issue, but here Chief Judge Rader was writing for the panel majority, and Judge Lourie dissented. The patent-in-suit was drawn to an electrical connector for junction boxes. One of the claim construction issues was whether “spring metal adaptor” should be defined by implication to require a “split.” Chief Judge Rader, writing for the court, concluded that “spring metal adaptor” should not be construed as requiring a “split.” Chief Judge Rader acknowledged that “[t]his court has, on occasion, supplied a definition by implication, if the specification manifests a clear intent to limit the term by using it in a manner consistent with only a single meaning.” 632 F.3d at 1254. However, Chief Judge Rader concluded that here there were several reasons for not requiring a “split” by implication. One was that although all of the drawings showed a “split,” only one of several embodiments was expressly described as having an “opening.” Chief Judge Rader noted that “even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words of expressions of manifest exclusion or restriction.” *Id.* quoting *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1381 (Fed. Cir. 2009). Chief Judge Rader further reasoned that “importing a split limitation improperly discounts substantive differences between the claims.”

Id. Chief Judge Rader noted that claim 1 called for a “spring metal adaptor being less than a complete circle,” while subject claim 8 omitted the less than a complete circle modifier. Chief Judge Rader concluded that “[t]his court has often acknowledged the fine line between reading a claim in light of the specification and importing a limitation from the specification into the claim. * * * Review of the intrinsic evidence reveals no intent to limit the term ‘spring metal adaptor’ by using it in a manner that excludes unsplit adaptors. This court therefore concludes that the district court erred in construing ‘spring metal adaptor’ to require a split. Instead, the contested term means ‘an adaptor made of spring metal.’ ” 632 F.3d at 1255-56.

Judge Lourie dissented-in-part, writing “[o]ne of the most difficult tasks in adjudicating patent cases is interpreting patent claims. We have propounded a variety of ‘rules’ for doing so, such as that claims should not be limited to preferred embodiments, * * * claim terms are interpreted in light of the specification of which they are a part, * * * and claims are interpreted according to their plain meaning, * * *.” 632 F.3d at 1257 (Lourie, J., dissenting-in-part). Judge Lourie added: “But the basic mandate is for claims to be interpreted in light of the specification of which they are a part because the specification describes what the inventors invented. * * * The specification is the heart of the patent. In colloquial terms, ‘you should get what you disclose.’ ” *Id.*

Judge Lourie further added: “The problem in claim interpretation is thus our focus on our muddy, conflicting, and overly formulaic rules, * * * when the real task of claim interpretation is to read the specification and determine what the inventors meant when they used the language they did. Obviously the claims define the scope of protection accorded the owners of a patent. * * * But in construing the claims we should avail ourselves of the knowledge we glean from the patent specification to see what the inventors disclosed as their invention. The bottom line of claim construction should be that the claims should not mean more than what the specification indicates, in one way or another, the inventors invented.” 632 F.3d at 1258 (Lourie, J., dissenting-in-part). Judge Lourie would have limited “spring metal adaptor” to one having a split.

Retractable Techs. and *Arlington Indus.* are but two recent examples of different approaches to the proper use of the specification in construing claims. Certainly the cases can be distinguished on their facts, and the dissents in both cases could be dismissed as simply a difference in interpretation. But Federal Circuit judges have acknowledged the difficulty of objectively reconciling the cases, and further a difficulty in objectively reconciling *Retractable Techs.* with *Phillips*.

Following the panel opinion in *Retractable Techs.*, a combined petition for panel rehearing and rehearing *en banc* was filed. Both were denied. *Retractable Techs. v. Becton, Dickinson & Co.*, 659 F.3d 1369 (Fed. Cir. 2011).

Judge Moore, in an opinion joined by Chief Judge Rader, dissented from the denial of rehearing *en banc*. Judge Moore urged:

- “Claim construction is the single most important event in the course of a patent litigation. It defines the scope of the property right being enforced, and is often the difference between infringement and non-infringement, or validity and invalidity.”
- “Despite the crucial role that claim construction plays in patent litigation, our rules are still ill-defined and inconsistently applied, even by us.”
- “Commentators have observed that claim construction appeals are ‘panel dependent’ which leads to frustrating and unpredictable results for both the litigants and the trial court.” (citing articles and blogs)
- “Nowhere is the conflict more apparent than in our jurisprudence on the use of the specification in the interpretation of claim language. The familiar mantra is ‘there is a fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims.’ * * *”
- “This case is a good vehicle to address two important claim construction principles: the role of the specification in construing the claims and whether deference should be given to the district court in the claim construction process.”

659 F.3d at 1370 (Moore, J., dissenting) (emphasis added).

Judge Moore, joined by Chief Judge Rader, further urged:

- “*Retractable* simply cannot be reconciled with our *en banc* decision in *Phillips*.”
- “*Retractable* illustrates a fundamental split within the court as to the meaning of *Phillips* and *Markman* as well as the proper approach to claim interpretation.”

659 F.3d at 1371, 1373 (Moore, J., dissenting).

Judge Moore, with Chief Judge Rader, reasoned:

- “It is clear that the words of the claim define the scope of the patented invention,” citing *Phillips*, 415 F.3d at 1312 (“It is a “bedrock principle” of patent law that “the claims of a patent define the invention to which the patentee is entitled the right to exclude.”) * * *.”
- “If the metes and bounds of what the inventor claims extend beyond what he has invented or disclosed in the specification, that is a problem of validity, not claim construction. It is not for the court to tailor the claim language to the invention

disclosed. The language is the language, and the same rules that apply to the construction of other legal instruments should apply to the construction of a patent claim.”

- “Applying these bedrock principles of interpretation, claim terms are to be given their plain and ordinary meaning to one of skill in the art. Quite frankly, I thought we resolved this in [*Phillips*].”
- “Of course the claims are to be construed in the context of the entire patent, including the specification. The specification may shed light on the plain and ordinary meaning. However, the specification cannot be used to narrow a claim term to deviate from the plain and ordinary meaning unless the inventor acted as his own lexicographer or intentionally disclaimed or disavowed claim scope.”
- “The circumstances in which the written description causes one of skill in the art to reject the plain meaning of a term are quite narrow. If the inventor has chosen a broad claim term that is not supported by his specification, the patent’s validity may be in jeopardy. But we cannot, as the court does in *Retractable*, redefine a claim term to match our view of the scope of the invention as disclosed in the specification. We are not the lexicographers.”

659 F.3d at 1370-71 (Moore, J., dissenting).

Judge Moore, joined by Chief Judge Rader, in urging that *Retractable* “simply cannot be reconciled” with the Federal Circuit’s *en banc* decision in *Phillips*, noted that the *en banc* court in *Phillips* held that the “baffles” that were at issue could be placed at any angle including at right angles. The *en banc* court in *Phillips* explained that there was nothing in the plain and ordinary meaning of “baffles” that precluded them from being oriented at right angles. The district court in *Phillips*, however, had held, *inter alia*, that a baffle must “extend inward from the steel shell walls at an oblique or acute angle to the wall face.” The *en banc* court concluded that one of ordinary skill in the art would not have construed the disclosure and claims to mean that a structure extending inward from one of the wall faces was a “baffle” if it was at an acute or obtuse angle, but was not a “baffle” if it was disposed at a right angle. The *en banc* court further noted that dependent claims limited the baffles to angles that would deflect projectiles, and thus the independent claims should not be so limited.

Judge Lourie, dissenting in *Phillips*, though, had urged that the district court’s opinion should be affirmed because an object of the invention was that the baffles should deflect bullets, and there was no disclosure that object would be achieved if the “baffles” were disposed at a right angle. 415 F.3d at 1329-30. Judge Moore noted that “[t]he dissent [by Judge Lourie in *Phillips*] made a compelling case—the specification is replete with angled baffles—and angling is necessary to achieve

the stated objective of deflection. Nonetheless, the majority of the *en banc* court held that baffles do not have to be angled. There was no disclaimer or special lexicography. Baffles were to be given their plain and ordinary meaning to one of skill in the art and the limitation in the specification ‘angled baffles’ would not be imported into the claim. With all due respect to the majority in *Retractable*, the case is inconsistent with *Phillips*, and we are bound to follow our *en banc* decision.” 659 F.3d at 1371-72 (Moore, J., dissenting).

Judge Moore further wrote: “The error in *Retractable* is the majority’s attempt to rewrite the claims to better conform to what it discerns is the ‘invention’ of the patent instead of construing the language of the claim. Indeed, the majority candidly explained that its construction, limiting ‘body’ to a one-piece body, ‘is required to tether the claims to what the specifications indicate the inventor actually invented.’ * * * The majority reaches this conclusion based on the examples disclosed in the specification that have a ‘one piece’ body, an indication in the specification that the invention ‘features a one piece’ body, and the disclosure that the syringe ‘can be molded as one piece.’ * * * Yet none of these statements in the specification suggest that ‘body’ actually means ‘one-piece body’; to the contrary, the use of the modifier ‘one piece’ strongly implies that the term ‘body’ does not inherently mean objects made solely of one piece. * * * Regardless of what ‘the inventor actually invented,’ it is clear that the only construction of the term ‘body’ that comports with the patent as a whole, as well as the plain meaning of the term, includes both single and multi-piece bodies.” 659 F.3d at 1372 (Moore, J., dissenting).

Judge O’Malley also dissented from the denial of rehearing *en banc*, urging that “[i]t is time to revisit and reverse our decision in *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (*en banc*),” to the effect that claim construction is a matter of law reviewed without deference to a district court’s conclusions. 659 F.3d at 1373. Judge O’Malley wrote that “[t]he fact * * * that the panel members could not agree on the proper claim construction in this case, despite careful consideration of their respective obligations under *Phillips*, underscores the complicated and fact-intensive nature of claim construction and the need to rethink our approach to it.” 659 F.3d 1375.

Ultimately, until the Federal Circuit chooses to revisit its *en banc* opinion in *Phillips*, that opinion controls over subsequent panel opinions that may – or may not – be consistent therewith.

**(h) Written Description and Enablement Support –
Claim Otherwise Invalid**

As discussed above, Accuray’s arguments focus on the specification, and urge that if claim 25 is not limited to the SARP algorithm, the claim would be invalid under § 112(1) for lack of written description and enablement support. Accuray argues, for example: “The only optimization algorithm disclosed in the specification is the simulated annealing algorithm (“SARP”). In fact, the specification uses the words ‘simulated annealing’ at least twenty times and ‘SARP’ at least six times. The specification refers to the Fast Simulated Annealing variant (FSA) of the simulated annealing algorithm as the preferred embodiment. * * * The specification provides no disclosure of any optimization algorithm other than the simulated annealing algorithm, and relies on Webb for the only detailed disclosure of how SARP optimizes beam weights.” Accuray’s Response [Dkt. 138] at 20-21. In a footnote, Accuray contends:

If the “optimized radiation beam arrangement” is construed to include beam geometry in addition to beam weights, the claims would be invalid under 35 U.S.C. 112, ¶ 1 for lack of written description and lack of enablement.

Id. at 20, n. 6. Accuray similar contends later in its response: “In the absence of any disclosure regarding beam geometry, BMI’s alternate construction would render the ‘283 patent invalid under 35 U.S.C. § 112 for lack of written description and/or lack of enablement.” *Id.* at 29.

In *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430 (Fed. Cir. 1988), however, the Federal Circuit expressly rejected an argument that limitations should be added to claims to preserve the validity of the claims. The Federal Circuit explained: “Although language in [some prior] decisions may have given the perception that claims are to be ‘saved’ from invalidity by reading extraneous limitations into them, * * * this court’s consistent approach in interpreting claims, and in rejecting resort to extraneous limitations from the specification, should have negated that perception by now. * * * Thus, the district court was wrong as a matter of law in reading into the claims at issue the two extraneous property limitations mentioned above.” *Id.* at 1434.

Once again, as explained in *SRI Int’l*, if limitations from the specification are to be read into the claims, “there would be no need for claims. Nor could an applicant, regardless of the prior art, claim more broadly than that embodiment. Nor would a basis remain for the statutory necessity that an applicant conclude his specification with ‘claims particularly pointing out and distinctly claiming

the subject matter which the applicant regards as his invention.’ * * * It is the claims that measure the invention.” 775 F.2d at 1121.

In *Phillips*, the Federal Circuit explained that “[w]hile we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction. * * * Instead, we have limited the maxim to cases in which ‘the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.’” 415 F.3d at 1327. See also *Nazomi Communs., Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1368-69 (Fed. Cir. 2005) (“[I]t is essential to understand the claims before their breadth is limited for purposes of preserving validity. Otherwise the construing court has put the validity cart before the claim construction horse.”).

The Federal Circuit has clearly counseled that claim construction may subsequently lead to a finding of invalidity, but the asserted potential for a finding of invalidity should not drive claim construction. There are a variety of practical reasons, but among those are that a showing of invalidity requires a clear and convincing level of proof. See *Microsoft*, 131 S. Ct. at 2242. Also, at least the question of enablement requires consideration of factors such as those noted above: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Wands*, 858 F.2d at 737.

In *Phillips*, for example, the Federal Circuit cited its prior opinion in *Liebel-Flarsheim Co. v. Medrad, Inc. (Liebel-Flarsheim I)*, 358 F.3d 898 (Fed. Cir. 2004), with approval (“although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments,” *Phillips*, 415 F.3d at 1323. In *Liebel-Flarsheim I*, the Federal Circuit (opinion by Judge Bryson, joined by Judges Lourie and Dyk), one of the issues was whether the claims, drawn generally to powered medical “injectors,” *i.e.*, syringes, in which a fluid was injected into a patient under high pressure necessarily required a “pressure jacket.” The Federal Circuit explained that the common specification of the patents-in-suit disclosed the use of pressure jackets, and the question was whether “the claims of those patents must be construed as limited to devices that use pressure jackets. In Medrad’s words, when ‘the subject matter claimed in

the patent-in-suit is the only subject matter described * * * that subject matter is the invention, and not simply a “preferred embodiment” of a broader invention.’” The Federal Circuit further explained that “[b]ased largely on the fact that [patents-in-suit] do not contain any description of an injector that lacks a pressure jacket, the district court construed all of the asserted claims from those two patents to require a pressure jacket, even though none of the asserted claims expressly refers to a pressure jacket. The district court concluded that ‘the specification makes clear that the injector includes a pressure jacket.’ Based on that observation, the court ruled that ‘the asserted claims do not cover a jacketless injector, even though the asserted claims might be considered broad enough to disclose a jacketless injector when read without reference to the specification.’” 358 F.3d at 901.

The Federal Circuit concluded that the district court had erred: “We have had many occasions to cite one or both of the twin axioms regarding the role of the specification in claim construction: On the one hand, claims ‘must be read in view of the specification, of which they are a part.’ * * * On the other hand, it is improper to read a limitation from the specification into the claims. * * * Although parties frequently cite one or the other of these axioms to us as if the axiom were sufficient, standing alone, to resolve the claim construction issues we are called upon to decide, the axioms themselves seldom provide an answer, but instead merely frame the question to be resolved. We have recognized that ‘there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.’ * * * As we have explained, ‘an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims “in view of the specification” without unnecessarily importing limitations from the specification into the claims.’ * * * That problem can present particular difficulties in a case such as this one, in which the written description of the invention is narrow, but the claim language is sufficiently broad that it can be read to encompass features not described in the written description, either by general characterization or by example in any of the illustrative embodiments.” 358 F.3d at 904-05.

The defendant’s, Medrad’s, arguments in *Liebel-Flarsheim I* were similar to Accuray’s arguments here. Namely, Medrad had argued that because all the embodiments described in the common specification of the patents-in-suit featured pressure jackets, the claims of those patents must be construed as limited to devices that use pressure jackets. Medrad argued that when “the subject matter claimed in the patent-in-suit is the only subject matter described * * * that subject

matter is the invention, and not simply a ‘preferred embodiment’ of a broader invention.” 358 F.3d at 905-06.

The Federal Circuit rejected that argument: “There are several answers to Medrad’s argument. The first is that this court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.” 358 F.3d at 906. The Federal Circuit found further support in the prosecution history. On the other hand, Leibel-Flarsheim having prevailed on claim construction did not necessarily mean that the claims were valid. In *Liebel-Flarsheim Co. v. Medrad, Inc. (Liebel-Flarsheim II)*, 481 F.3d 1371 (Fed. Cir. 2007), the Federal Circuit explained that the district court after remand in *Liebel-Flarsheim I* had concluded that the claims were invalid under 35 U.S.C. § 112(1) as lacking proper written description and enablement support – *i.e.*, there was no written description or enablement support for a “jacketless” injector. *Id.* at 1375. The Federal Circuit agreed that there was no enabling support for a jacketless injector. *Id.* at 1380.

Accordingly, the issue of claim construction is addressed here. Whether that construction leads to potential invalidity under 35 U.S.C. § 112(1) will have to await another day.

(2) Claim Language

(a) Ordinary and Customary Meaning

The Federal Circuit in *Phillips* reaffirmed the analysis from *Vitronics*, which seeks to ascertain the ordinary and customary meaning of claim terms, as such terms would be understood by one of ordinary skill in the art who has read the specification and prosecution history. In doing so, there are certain analytical tools available. For example, the context of how a disputed term is used in the actual claim language may allow a court to determine the patentee’s intended meaning.

For ease of reference, claim 25, once again, provides:

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

Although Accuray urges that “[a] claim term is generally given its ‘ordinary and customary meaning,’ that is, ‘the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention,’” Accuray’s Response [Dkt. No. 138] at 15, Accuray’s description of the technology indicates that the language used in claim 25 was well-known and understood by persons of ordinary skill in the art.

(b) Accuray’s Description of the Technology

Accuray, relying on a declaration by its expert Dr. Rosen, for example, explains that “[o]ptimization algorithms are mathematical algorithms used in inverse planning and IMRT [intensity-modulated radiation therapy] to find the set of beam weights for each beam that produces the best dose distribution for a particular patient.” Accuray’s Response [Dkt. No. 138] at 6. Accuray also explains that “there is an extensive body of literature exploring the use of many optimization algorithms.” *Id.*

Accuray explains that “[e]very optimization problem must have a goal,” and “[a] ‘cost’ function is the mathematical description of that goal.” *Id.* at 6-7. According to Accuray, “[e]very potential solution to the problem has an associated cost, which is calculated by the cost function.” *Id.* at 7.

Accuray says that “[s]ome algorithms are limited in what cost functions they can optimize, and some algorithms are more efficient for a particular cost function than others.” *Id.* Accuray also explains that “[e]very optimization problem also has independent parameters (variables) that are changed to generate potential solutions to the problem.” *Id.* Accuray says that “[i]n radiation treatment planning, these independent variables are most often beam weights.” *Id.*

Accuray explains that “[a] variety of cost functions had been used in radiation therapy treatment plan optimization before the filing date.” *Id.* Accuray further explains that “[i]f the relationship can be written as an equation with the value of the cost on one side and the variables on the other side, then the cost function is said to be ‘analytic’. Otherwise, the cost function is ‘non-analytic.’” *Id.*

Accuray explains that “[m]any optimization methods, such as linear programming methods, will not work with non-analytic cost functions.” *Id.* at 7-8. Accuray says that “[i]n a linear cost function, there is a linear relationship between the cost and the variables,” while “[i]n contrast, in a non-linear cost function, the cost does not have a linear relationship with the variables.” *Id.* at 8. Accuray explains that when a cost function is non-linear it requires a certain type of algorithm and that stochastic algorithms, such as simulated annealing, are used. *Id.* Accuray says that “[a]n example of a non-linear cost function is one that uses dose volume variables such as CDVH curves or the partial volume data from CDVH curves.” *Id.*

Accuray further says that “[i]n the mid-1990’s, many optimization methods were known in the art for producing an optimized solution, including both analytic and stochastic methods.” *Id.* Accuray explains that “[a]nalytic algorithms, such as linear programming and quadratic programming, solve the problem directly through algebraic operations,” while “[o]ther algorithms are non-analytic, and use a search method to solve problems.” *Id.* At 9.

Accuray explains that “[o]ther non-analytic algorithms are stochastic, such as simulated annealing and genetic algorithms.” *Id.* at 9-10. Accuray says that simulated annealing was appealing for optimization because, *inter alia*, “it is suitable for use with virtually any cost function, even non-analytic or non-linear ones.” *Id.* at 10. According to Accuray, “[t]he advantages of simulated annealing and its variants, including its relative simplicity and the fact that it was well suited for complex many-dimensional cost functions, were well known in the art prior to the filing date of the ‘283 patent.” *Id.*

Accuray says that “[o]ptimization in radiation therapy is almost exclusively focused on finding the beam weights for each beamlet of each beam that together result in the best dose distribution for a patient.” *Id.* at 11. Accuray explains that “[i]n radiation treatment planning, there are two basic conflicting goals. The goal for the target is a high dose to destroy the disease, but the goal for the normal tissues is a low dose to avoid radiation damage and the resulting treatment

complications.” *Id.* Accuray further explains that “[t]hese conflicting goals can be implemented through the cost function in one of three ways: (1) the cost function may focus on delivering a high dose to the target and use constraints to limit the amount of radiation to the normal tissues; (2) the cost function may focus on minimizing the doses to the normal tissues subject to constraints that force a minimum dose to the tumor; or (3) the cost function may include doses to both the target and normal structures and use weighting factors to drive the solution to the desired compromise.” *Id.* at 11-12. In a footnote, Accuray says that “[t]he ‘283 patent describes the third approach, using weighting factors applied to the zones of the CDVHs for both targets and structures.” *Id.* at 12, n. 4.

Accuray urges that the ‘283 patent “acknowledges that other than that modified cost function, everything in the ‘283 patent was known in the art,” *Id.* at 14 citing col. 12, lines 34-35. That portion of the ‘283 patent says:

(Fast Simulated Annealing) techniques. Except for the foregoing detailed description of the cost function utilized in the present system, the details of the foregoing simulated annealing techniques are known in the art and are described in such publications as “Optimization of Conformal Radiotherapy Dose Distributions by Simulated Annealing”, S. Webb, Physics and Medical Biology, Vol. 34, PP. 1349–1370 (1989); and “Optimization of Conformal Radiotherapy Dose Distributions by Simulated Annealing: 2. Inclusion of Scatter in the 2d Technique”, S. Webb, Physics and Medical Biology, vol. 36, pp. 1227–1237, (1991), which publications are incorporated herein by reference. A suitable computer is utilized in performing the Plan Optimization step, as well as the other steps of the radiation planning system.

Accuray urges that “[e]very element of the claimed invention was known in the art, with the possible exception of the specific ‘modified’ cost function which uses partial volume data input to create CDVH’s, divides those CDVH’s into zones, weights those zones differentially, and uses those parameters to find the cost of each proposed set of beam weights created by the simulated annealing algorithm. Accordingly, the claims must be limited to the specific cost function and the specific optimization algorithm disclosed in the specification.” Accuray Response [Dkt. No. 138] at 14.

Once again, Accuray’s description of the technology indicates that the language used in claim 25 was well-known and understood by persons of ordinary skill in the art.

(c) Courts Construe Disputed Terms and Phrases But Do Not Rewrite Claims

Turning then to Accuray's contention that "the claims must be limited to the specific cost function and the specific optimization algorithm disclosed in the specification," courts quite simply do not have the power to rewrite claims. In *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371 (Fed. Cir. 2004), for example, the claim-at-issue called for "heating the resulting batter-coated dough to a temperature in the range of about 400 degrees F. to 850 degrees F." which if taken literally, as counsel noted, would result in a something resembling a charcoal briquette, rather than having a "light, flaky, crispy texture" as disclosed in the patent. Nevertheless, the Federal Circuit emphasized that "[t]his court, however, repeatedly and consistently has recognized that courts may not redraft claims, whether to make them operable or to sustain their validity." *Id.* at 1374.

Although there are instances in which a court may correct so-called "Essex-type errors" (named after *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 442 (1926)), see e.g., *Ultimax Cement Manufacturing Corp. v. CTS Cement Manufacturing Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009), namely certain obvious errors, the instances in which a court may do so are limited. See *Novo Industries L.P. v. Micro Molds Corp.*, 350 F.3d 1348 (Fed. Cir. 2003); *Hoffer v. Microsoft Corp.*, 406 F.3d 1365 (Fed. Cir. 2005)(per curiam); *Group One, Ltd. v. Hallmark Cards, Inc. (Group One II)*, 407 F.3d 1365 (Fed. Cir. 2005)(per curiam); *CBT Flint Partners, LLC v. Return Path, Inc.*, 654 F.3d 1353 (Fed. Cir. 2011).

Claim 25, as drafted, may ultimately be adjudged invalid for lack of novelty under § 102, or as drawn to subject matter that would have been obvious under § 103, or as lacking commensurate written description and/or enabling support under § 112(1), or for some other reason. But, as discussed above, assertions of invalidity require both a "clear and convincing" quantum of proof, and an evaluation of factors such as, in the instance of enabling support, "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims," *Wands*, 858 F.2d at 737, or in the case of obviousness, "the scope and content of the prior art * * *; differences between the prior art and the claims at issue * * *; and the level of ordinary skill in the pertinent art * * *," as well as "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., * * *." *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

As noted above, per *Phillips* and *Nazomi*, claim construction – the horse – drives validity – the cart – not *vice versa*. As in *MagSil*, *Liebel II*, and other cases, when a patentee urges a broad claim construction, the patentee does so at its peril. The claims may – or may not – ultimately be held invalid as Accuray contends. But that requires both a different type of proof, and level of proof, than required during *Markman*-type claim construction.

In short, Accuray has not shown that anything in the express language of the claims, construed according to the “ordinary and customary” meaning of that language, requires limiting claim 25 to using SARP. Other claims lend further support to that conclusion.

(d) The Pertinence of Other Asserted and Non-Asserted Claims

The Federal Circuit in *Phillips* reaffirmed that other asserted and non-asserted claims may be used to discern a patentee’s intended meaning. Again, § 112(2) requires that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” (emphasis added). Just as the written description and enablement portions of the specification may provide guidance, both the asserted and non-asserted claims in a patent may provide guidance to the court on what the applicant “regards as his invention.”

Although frequently referred to as “claim differentiation,” more broadly, as the Federal Circuit discussed in *Phillips*, assessing the differences among asserted and non-asserted claims may provide an insight to what the patentee actually intended to claim. In that respect, as the Federal Circuit also recognized in *Phillips*, assessing the differences among asserted and non-asserted claims aids in distinguishing between (1) reading limitations from the specification into the claims, versus (2) reading claims in light of the specification.

In that regard, assessing the differences among asserted and non-asserted claims may be used, both in the traditional context of a dependent claim adding a limitation to an independent claim, thus leading to at least an implication (many cases say a “presumption”) that the patentee intended the independent claim to be broader than the dependent claim. But assessing the differences among asserted and non-asserted claims may be used in other contexts as well, for example comparing various independent claims, or various claim groupings.

Specifically, the *en banc* Federal Circuit in *Phillips*, as noted above, advised that “[d]ifferences among claims can also be a useful guide in understanding the meaning of particular claim terms.” 415 F.3d at 1314. That includes both the context of differences between independent-dependent claims, and the context of differences among claims, both asserted and unasserted, although the analysis may differ among the two. That is, the clearest case of using a differentiation among claims to ascertain what the patentee truly “regards as his invention” under § 112(2), is when a dependent claim narrows a single limitation in a parent independent claim – for example, a dependent claim that provides, in reference to a “leg member” in a parent independent claim, “wherein the leg member is tapered.” That clearly indicates that the patent drafter intended that “leg member” in the independent claim could be tapered or not tapered. However, “[d]ifferences among claims” includes other than the independent-dependent claim relationship. For example, suppose one independent claim called for “a leg member that is tapered” or “a tapered leg member,” while another independent claim called for “a leg member.” The absence of “tapered” in the second independent claim at least raises the question whether the patentee intentionally chose to claim “leg member” more broadly in the second independent claim, and include leg members that were not tapered. Assume, in both examples, all drawings and description in the patent showed or described a tapered leg member. The difference among the claims, though, in both examples suggests that the patentee did not intend to limit the claim to the disclosed embodiment.

And, indeed, as discussed above, a patentee may choose to claim an invention more broadly than the specific examples disclosed in the specification. Of course, such a claim may or may not be valid for lack of written description/enablement support, as also discussed at length above.

The relative importance of analyzing differences among the claims of a patent – both asserted and non-asserted – in an effort to discern the true scope of a claim, has evolved over the years since the Federal Circuit was created in 1982. Indeed, in terms of language, dramatically so – *vis-à-vis* relative reverence to the analysis. But not so much in application.

Not too long after creation of the Federal Circuit in 1982, then-Chief Judge Markey writing for the court in *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570 (Fed. Cir. 1985), and responding to the district court’s comment that “as a general rule a limitation cannot be read into a claim to avoid infringement,” wrote emphatically: “Where, as here, the limitation sought to be ‘read into’ a claim already appears in another claim, the rule is far more than ‘general.’ It is fixed. It is long and well

established. It enjoys an immutable and universally applicable status comparatively rare among rules of law. Without it, the entire statutory and regulatory structure governing the drafting, submission, examination, allowance, and enforceability of claims would crumble.” *Id.* at 1574. Subsequent cases, though, have not only been far less emphatic, but have, from one perspective, relegated differentiation among claims to being a “guideline” that is sometimes applied and sometimes not (and the distinction between the two is many times not clear), rather than a rigid rule, *see e.g., Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991) (“Claim differentiation is a guide, not a rigid rule.”), *Comark Communs., Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (“While we recognize that the doctrine of claim differentiation is not a hard and fast rule of construction * * *”), *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1359 (Fed. Cir. 2012)(*en banc* on a different issue) (opinion by Circuit Judge Lourie) (“claim differentiation is ‘not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history,’ ” quoting *Seachange Int’l, Inc. v. C-Cor, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005)). One might conclude from those and like cases that differentiation among claims has evolved from “an immutable and universally applicable” principal to a principal enjoying a somewhat lesser role. Or, perhaps, more precisely, the relative role of differentiation among claims has not changed so much, but rather the Federal Circuit has added the explanation that whatever suggestion or “presumption” that might arise from differentiation among claims may be overcome by other outweighing, intrinsic evidence (in terms of clarity, unambiguousness, or other reasons why some evidence might outweigh other evidence), from the specification and/or prosecution history. That is, if a contrary construction is “dictated” (in the above example of “a leg member,” for instance, if during prosecution the patentee unambiguously argued that “leg member” was limited to a “tapered leg member”), then any suggestion or “presumption” arising from differentiation among claims is overcome by contrary evidence that outweighs any suggestion or “presumption” arising from differentiation among claims. In that instance, characterizing differentiation among claims as a “guideline” as opposed to a “rigid rule” is simply saying that whatever construction that may result from differentiating among claims may be outweighed by other intrinsic evidence.

Moreover, whether differentiation among claims is characterized as a “guideline” rather than a “rigid rule,” does not diminish the importance of the Federal Circuit’s advice in *Phillips* that “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term. * * * Because claim terms are normally used

consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” 415 F.3d at 1314. Rather, in analyzing claims, differences among claims must not be blindly used to jump to conclusions *vis-à-vis* claim construction. There may be differences between claims that do not necessarily indicate a patentee’s intention for one claim to assert a limitation broadly, while for another claim to assert the same limitation narrowly. After all, claims are considered as a “whole.” Moreover, the weight of other intrinsic evidence may overcome whatever weight is given to differentiation among claims.

In all events, as the Federal Circuit in *Phillips* pointed out, differentiation among claims is at least one “tool” that a court may use in distinguishing between (1) improperly importing limitations from the specification into a claim, and (2) interpreting a claim “in light” of the specification. But, again, the specification and prosecution history remain important.

For instance, in the above example of (1) an independent claim calling for a “leg member,” and a dependent claim calling for “wherein said leg member is tapered,” and (2) one independent claim calling for a “leg member” and a second independent claim calling for “a tapered leg member,” claim differentiation in both instances alone may suggest that when the patentee referred to “leg member” the patentee was clearly intending to claim a leg that may or may not be tapered. If the specification and drawings only disclosed tapered legs, that *per se* would not necessarily limit claims to a “leg member” to a “tapered leg member” because both *Phillips* and other cases repeatedly emphasize that claims are not necessarily limited to the disclosed embodiments – even if there is only one embodiment. But suppose the specification includes a lexicographical reference, such as “herein, the term ‘leg member’ means a ‘tapered leg member.’” Clearly, that lexicographical reference overcomes any suggestion raised by claim differentiation. Or, suppose the specification includes words to the effect that “the present invention comprises a tapered leg member.” That too may clearly indicate that “the invention” was limited to a “tapered leg member” and claims calling simply for a “leg member” should be construed as implicitly calling for a “tapered leg member.” Or suppose that during prosecution claims calling for “leg member” were rejected over prior art showing such a “leg member,” and the applicant argued for patentability by asserting that the prior art did not disclose a “tapered leg member.” In that instance too, the prosecution history may be deemed to clearly indicate that “leg member” in the claims should be implicitly construed as “tapered leg member” although doing so would run afoul of the claim differentiation guideline.

Indeed, that was the situation in *Seachange Int'l, Inc. v. C-Cor, Inc.*, 413 F.3d 1361 (Fed. Cir. 2005). The representative claim-at-issue, claim 37, called for a “network for data communications” which the district court construed to mean “establishing data communications between every pair of processor systems in the distributed computer system using any kind of network.” The question was whether the claim should be limited to “point-to-point” communications. The Federal Circuit agreed with the district court that the express language of the claim did not suggest that “network” was limited to networks employing direct, point-to-point interconnections. Seachange agreed and urged that was further supported by claim differentiation. Claim 1 called for “interconnecting each one of said processor systems in a point-to-point two way channel interconnection with each other one of said processor systems.” Claim 37 was identical to claim 1, except that it required only that the interconnection be through a “network for data communications.” The Federal Circuit noted that “[t]he doctrine of claim differentiation creates a presumption that these limitations in claim 1 and claim 37 are of different scope and suggests that claim 37 does not require point-to-point, two-way channel interconnections. However, that presumption is not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history.” 413 F.3d at 1369.

Turning to the specification, C-COR had argued that the written description disclosed only point-to-point interconnections and that the point-to-point interconnections achieved a necessary objective of the invention. The Federal Circuit “agree[d] with C-COR that the written description consistently refers to the network interconnections as point-to-point * * *,” and that “point-to-point interconnections achieve an object of the invention in that they increase read and write bandwidth,” but concluded that it was “unclear whether these references to point-to-point are simply the consistent description of one possible embodiment or a description of the invention itself.” *Id.* at 1370.

The Federal Circuit then turned to the prosecution history. In response to a prior art rejection over, *inter alia*, a patent to Benner, the applicants had argued: “Benner does not describe that each of the processor systems are interconnected in a point to point two-way channel interconnection with each other one of the processor systems as recited in Applicant’s claim 1.” Later, in responding to a third-party protest, the applicant urged that “nowhere in [Gardner – an asserted prior art reference] does the patentee describe or suggest a store/retrieve two-way point-to-point configuration.” The Federal Circuit noted that “C-COR argues that Applicant’s arguments

made during prosecution narrowed the scope of the ‘network for data communications’ limitation in claim 37 (40) to cover only a point-to-point network. Seachange counters that Applicant’s arguments did not amount to a clear and unambiguous disclaimer of claim scope.” The Federal Circuit concluded: “We agree with C-COR.” *Id.* at 1372.

On the other hand, the Federal Circuit in *Seachange* also emphasized, in connection with other limitations, that it was improper to read limitations from the specification into the claims. The district court in *Seachange* had construed “distributed computer system” to require that there be “a stand alone computer in each processor system.” The Federal Circuit disagreed concluding “[b]ecause it is improper to import a limitation into a claim where the limitation has no basis in the intrinsic record, *** we conclude that the district court erred in requiring that each processor system ‘stand-alone,’ ***. ‘Distributed computer system’ should be given its ordinary meaning, which both parties agree is ‘a computer system in which several interconnected computers share computing tasks assigned to the system.’” *Id.* at 1376.

Similarly, the district court had construed “processor systems” to require that each system have “at least one [CPU] capable of running application type software, and at least one mass storage subsystem.” The Federal Circuit concluded that “[b]ecause we do not import limitations from a preferred embodiment, *** each ‘processor system’ need not have a CPU capable of running application software.” *Id.* at 1377.

The Federal Circuit in *Seachange*, in discussing claim differentiation, wrote:

The doctrine of claim differentiation stems from “the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope.” *** Although the doctrine is at its strongest “where the limitation sought to be ‘read into’ an independent claim already appears in a dependent claim,” *** there is still a presumption that two independent claims have different scope when different words or phrases are used in those claims, ***. However, the doctrine “only creates a presumption that each claim in a patent has a different scope; it is not a hard and fast rule of construction.” *** “The doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence. *** Claims that are written in different words may ultimately cover substantially the same subject matter.”

Id. at 1368-69. Judge Lourie, writing for the court in *Marine Polymer Techs.*, quoted only a portion of *Seachange*, i.e., “claim differentiation is ‘not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history.’” As discussed above, the

written description in *Seachange* disclosed only point-to-point interconnections and that the point-to-point interconnections achieved a necessary objective of the invention, but the Federal Circuit nevertheless concluded that alone was insufficient to overcome the “presumption” that arose from claim differentiation. In *Seachange*, however, the prosecution history clearly indicated a disclaimer of claim scope. However, as to other claim limitations, the Federal Circuit emphasized that “we do not import limitations from a preferred embodiment.”

With that background, in evaluating differences among claims, it is helpful to look at claim 1 and its dependent claims versus claim 25. Claim 1 has twelve dependent claims (claims 2-13), and claim 25 has three dependent claims (claims 26-28). Pertinent dependent claims are reproduced below:

<p>1. A method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising the steps of:</p> <p>using a computer to computationally obtain a proposed radiation beam arrangement;</p> <p>using a computer to computationally change the proposed radiation beam arrangement iteratively,</p> <p>incorporating a cost function at each iteration to approach correspondence of a <u>CDVH</u> associated with the proposed radiation beam arrangement to a <u>CDVH</u> associated with a predetermined desired dose prescription; and</p> <p>rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired prescription and accepting the change of the proposed beam arrangement if</p>	<p>25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:</p> <p>a computer, adapted to computationally obtain a proposed radiation beam arrangement,</p> <p>the computer further adapted to computationally change the proposed radiation beam arrangement iteratively,</p> <p>wherein the proposed radiation beam arrangement is changed by changing the beam weights,</p> <p>the computer further adapted to incorporate a cost function at each iteration to approach correspondence of <u>partial volume data</u> associated with the proposed radiation beam arrangement to <u>partial volume data</u> associated with a pre-determined desired dose prescription, and</p> <p>the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the</p>
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the change of the proposed beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

2. The method of claim 1 wherein the cost function is obtained by the steps of:

determining a CDVH associated with the desired dose prescription;

assigning zones to each CDVH;

assigning weights to each zone, applicable to the CDVHs associated with both the desired dose prescription and the proposed radiation beam arrangement;

calculating a zone cost for each target and each structure, according to the following formula:

$$C_z = W_z * (A_p / A_d),$$

where C_z is the cost for the current zone, W_z is the weight assigned to the current zone, A_p is the area or length of the current zone of the proposed CDVH, and where A_d is the area or length of the current zone of the desired CDVH;

calculating a target or structure cost for each target or structure, according to the following formula:

$$C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}, \text{ and}$$

$$C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$$

where C_S and C_T are the cost for each structure or zone, and C_{z1} , C_{z2} , C_{z3} , and C_{zn} are the costs calculated for each zone of the first, second, and third, through nth zone of each target or structure; and

calculating a total cost for the change in the proposed radiation beam arrangement, according to the following formula:

proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

26. The apparatus of claim 25, wherein the partial volume data is represented as a CDVH.

$$C_{Total} = C_S + C_T,$$

where C_{Total} is the total cost of the proposed change to the radiation beam arrangement.

3. The method of claim 1, wherein the proposed radiation beam arrangement is calculated using simulated annealing radiation therapy planning methods.

4. The method of claim 1, wherein the proposed radiation beam arrangement is changed by changing the beam weights.

5. The method of claim 2, wherein the proposed radiation beam arrangement is calculated using simulated annealing radiation therapy planning methods.

6. The method of claim 1, further comprising the step of applying the optimized radiation beam arrangement to the patient with a conformal radiation therapy apparatus.

7. The method of claim 2, further comprising the step of applying the optimized radiation beam arrangement to the patient with a conformal radiation therapy apparatus.

8. The method of claim 3, further comprising the step of applying the optimized radiation beam arrangement to the patient with a conformal radiation therapy apparatus.

9. The method of claim 5, further comprising the step of applying the optimized radiation beam arrangement to the patient with a conformal radiation therapy apparatus.

27. The apparatus of claim 25, further comprising:

a conformal radiation therapy apparatus in communication with the computer for applying the optimized radiation beam arrangement to the patient.

28. The apparatus of claim 27, wherein the partial volume data is represented as a CDVH.

As is clear from the foregoing, dependent claims 3 and 5 further call for the “proposed radiation beam arrangement” to be “calculated using simulated annealing radiation therapy planning methods.” Where the patentees claimed use of SARP, they did so expressly.

Independent/dependent claim pairs 14 and 15, and 18 and 19 similarly differentiate between obtaining “proposed” beam data generally, and doing so by using SARP:

14. A method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while

18. A method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while

minimizing radiation of a structure volume in a patient, comprising the steps of:

(a) determining a desired CDVH associated with each target and structure;

(b) using a computer to iteratively compare a cost of a radiation beam arrangement proposed during a given iteration to a radiation beam arrangement proposed during the previous iteration based on the relative costs associated with the proposed radiation beam arrangement, the costs being calculated by:

(1) determining a CDVH associated with each target and structure based on the proposed radiation beam arrangement of a given iteration;

(2) assigning cost zones to the desired CDVH and the proposed CDVH of a given iteration associated with each target and structure;

(3) assigning a weight value to each cost zone of each CDVH associated with each target and structure;

(4) for each target and structure, multiplying the weight value of each zone by the quotient of a value representing the area of the zone of the CDVH associated with the proposed radiation beam arrangement and a value representing the area of the zone of the CDVH associated with the desired radiation beam arrangement;

(5) summing the results of step (4) for each zone of each CDVH of each target and structure to obtain a total dosage cost;

minimizing radiation of a structure volume in a patient, comprising the steps of:

determining a desired CDVH for each of at least one target or structure, representing the desired cumulative effect of a radiation dose to be applied to the patient;

calculating a proposed radiation beam arrangement proposed to be applied to the patient, associated with a total dosage cost;

creating a proposed CDVH for each of the at least one target or structure, representing the cumulative effect of the proposed radiation beam arrangement;

assigning a plurality of cost zones for each of the desired CDVHs;

assigning a zone weight for each of the plurality of cost zones of each of the CDVHs;

determining a zone cost value representing a zone cost for each cost zone of each CDVH of each target and structure for each of the plurality of cost zones of each of the desired CDVHs by multiplying a value representing the cost zone's zone weight by a value representing the quotient of a value representing the cost zone's zone area bounded by the proposed CDVH and a value representing the cost zone's zone area bounded by the desired CDVH;

determining a total target cost value representing a cost of the proposed radiation beam arrangement for each of the at least one target by summing the zone cost values of each of the at least one target;

determining a total structure cost value representing a cost of the proposed radiation beam arrangement for each of the at least one structure by summing the zone cost values of

<p>(c) accepting the proposed radiation beam arrangement of a given iteration if the total dosage cost of a given iteration is less than the total dosage cost of the previous iteration;</p> <p>(d) rejecting the proposed radiation beam arrangement of a given iteration if the total dosage cost of a given iteration is greater than the total dosage cost of the previous iteration; and</p> <p>(e) repeating steps b-d until the proposed radiation beam arrangement has a total dosage cost value within an acceptable level to obtain an optimized radiation beam arrangement.</p> <p>15. The method of claim 14, wherein the proposed radiation beam arrangement is calculated using <u>simulated annealing radiation therapy planning methods</u>.</p>	<p>each of the at least one structure; and</p> <p>determining a total dosage cost value representing the total cost of the proposed radiation beam arrangement by summing each target cost value and each structure cost value.</p> <p>19. The method of claim 18, wherein the proposed radiation beam arrangement is calculated using <u>simulated annealing radiation therapy planning methods</u>.</p>
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With respect to calculating the “optimized radiation beam arrangement,” independent claim 40 is drawn to a “method of determining an optimized radiation beam arrangement * * *.” Claim 43, which depends directly from claim 40, calls for the “optimized radiation beam arrangement” to be “calculated using simulated annealing radiation therapy planning methods, or SARP methods.” Claim 45, which depends indirectly from claim 40, requires the same thing.

40. A method of determining an optimized radiation beam arrangement for applying radiation to at least one tumor target volume while minimizing radiation of at least one structure volume in a patient, comprising the steps of:

determining desired partial volume data for each of the at least one target volume and structure volume associated with a desired dose prescription;

entering the desired partial volume data into a computer;

in response to the desired partial volume data, using the computer to computationally approximate desired CDVHs for each of the at least one target and structure associated with the desired dose prescription; and

using the computer to computationally calculate the optimized radiation beam arrangement associated with the CDVHs approximated by the computer.

41. The method of claim 40, wherein the desired CDVHs are computationally constructed by the computer based on numerical values representing the partial volume data entered into the computer.

42. The method of claim 40, further comprising the step of applying the optimized radiation beam arrangement to the patient with a conformal radiation therapy apparatus.

43. The method of claim 40, wherein the optimized radiation beam arrangement is calculated using simulated annealing radiation therapy planning methods.

44. The method of claim 40, wherein the CDVHs approximated by the computer are approximated by the steps of:

using the computer to computationally obtain a set of proposed beam weights;

using the computer to computationally change the set of proposed beam weights iteratively, incorporating a cost function at each iteration to determine a cost of the change to the set of proposed beam weights; and

rejecting the change to the set of proposed beam weights if the change to the set of proposed beam weights leads to a lesser correspondence to the desired CDVHs and accepting the change to the set of proposed beam weights if the change to the set of proposed beam weights leads to a greater correspondence to the desired CDVHs.

45. The method of claim 44, wherein the optimized radiation beam arrangement is calculated using simulated annealing radiation therapy planning methods.

Although differentiating between asserted and non-asserted claims may have been relegated in some cases to a “guideline” and not a “rigid rule” – perhaps because in those cases the court chose not to apply that analysis – evaluating the differences among claims remains an objective source for determining “the subject matter which the applicant regards as his invention.” § 112(2). Claim 25 is not by its express terms limited to SARP, and difference between various independent claims, which do not expressly call for SARP, and dependent claims, some of which do expressly call for SARP, indicate that claim 25 is not limited to SARP.

(3) Specification

As the Federal Circuit noted in *Phillips*, the claims “do not stand alone,” and “ ‘must be read in view of the specification, of which they are a part.’ ” *Id.*, 415 F.3d at 1315 (quoting *Markman*, 52 F.2d at 979). Indeed, “[i]n light of the statutory directive that the inventor provide a ‘full’ and ‘exact’

description of the claimed invention, the specification necessarily informs the proper construction of the claims.” *Phillips*, 415 F.3d at 1316. That is, as the Federal Circuit explained in *Merck & Co. v. Teva Pharms. USA, Inc.*, “[a] fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification, of which they are a part.” 347 F.3d 1367, 1371 (Fed. Cir. 2003); *Phillips*, 415 F.3d at 1316 (citing *Merck & Co.*).

As noted above, Accuray urges that claim 25 should be limited to SARP in view of the specification’s repeated reference to determining an optimized radiation beam arrangement by using SARP and the disclosed cost function, and the specification’s lack of disclosure of any other method for determining an optimized radiation beam arrangement. In other words, Accuray contends, the specification requires limiting claim 25 to SARP.

(a) Disclosure of SARP

There appears to be no dispute that SARP is the only optimization method disclosed in the section of the specification entitled “Detailed Description of the Invention.” However, that fact alone does not limit claim 25. The Federal Circuit *en banc* has “expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.” *Phillips*, 415 F.3d at 1323 (citations omitted). See *Kara Tech., Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) (“The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.”).

The rationale, as the Federal Circuit *en banc* has explained, is that “the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case.” *Phillips*, 415 F.3d at 1323 (citations omitted). And, “[m]uch of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. The manner in which the patentee uses a term within the specification and claims usually will make the distinction apparent.” *Id.*

For example, “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Id.* In other cases, the Federal Circuit *en banc* has explained, “the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor’s intention, as expressed in the specification, is regarded as dispositive.” *Id.* See *Interdigital*, slip op. at 10 (“The plain meaning of claim language ordinarily controls unless the patentee acts as his own lexicographer and provides a special definition for a particular claim term or the patentee disavows the ordinary scope of a claim term either in the specification or during prosecution.”). Also, as Judge Rader acknowledged in *Retractable Techs.*, there are cases in which the Federal Circuit has “supplied a definition by implication, if the specification manifests a clear intent to limit the term by using it in a manner consistent with only a single meaning.” 632 F.3d at 1254.

Here, the specification indicates in a number of places that the patentees did not “intend[] for the claims and the embodiments in the specification to be strictly coextensive.” *Phillips*, 415 F.3d at 1323. Although SARP is the only optimization method disclosed in the section of the specification entitled “Detailed Description of the Invention,” the patentees prefaced that section with a statement that

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as to be defined by claims to be filed in a non-provisional application.

Col. 8, lines 51-57. In some instances, such language may be viewed as “boilerplate” or “rote language,” and discounted accordingly. In *Arlington Indus.*, for example, Judge Lourie, J., dissenting-in-part, wrote that “[t]he fine distinctions we often make concerning what is disclosed in a specification arise of course from how the inventors describe aspects of their invention. They describe embodiments of the invention, preferred embodiments, specific examples, sometimes using language broader than expressed in the claims to describe embodiments, and finally, in frequent boilerplate, indicate that the invention isn’t to be limited to what is expressly disclosed (as if they were unable to describe anything else they actually invented). Questions then arise as to whether an invention is limited to a preferred embodiment, or to the disclosed embodiments, or to what the specification in some language indicates is part of the invention. But, at bottom, we are reading a

patent specification to see what the inventors invented, what they disclosed, and how they conveyed that information. A patent is a teaching document. In almost all cases, the inventors, and their patent solicitors, knew what was invented and generally disclosed their invention in competent language.” 632 F.3d at 1258.

However, such language may be given weight where the specification provides support for what the “boilerplate” language says. In *Dealertrack, Inc. v. Huber*, 674 F.3d 1315 (Fed. Cir. 2012), for example, the Federal Circuit concluded that the district court had improperly excluded the Internet from its construction of “communications medium.” The Federal Circuit reiterated that “disclosure of multiple examples does not necessarily mean that such list is exhaustive or that non-enumerated examples should be excluded.” The court noted that the section in which the list of examples was found was entitled “Detailed description of the preferred embodiment(s),” and that “the first paragraph of the section says: ‘It should be kept in mind that the following described embodiment(s) is only presented by way of example and should not be construed as limiting the inventive concept to any particular physical configuration.’” “While in some circumstances this may be taken as rote language,” the Federal Circuit wrote, “the additional context of the list cannot: ‘Although illustrated as a wide area network, it should be appreciated that the communications medium could take a variety of other forms, for example, a local area network, a satellite communications network, a commercial value added network (VAN) ordinary telephone lines, or private leased lines * * *. The communications medium used need only provide fast reliable data communication between its users.’” The Federal Circuit concluded that “[t]he natural reading of this paragraph, and the only reading that does not violate this court’s repeated prohibition against importing limitations from the specification, is of a non-exhaustive list that, if anything, broadens the definition of ‘communications medium.’” The Federal Circuit further noted that neither party disputed that the Internet was a network for transferring data as of the time of filing of the application, and “[t]o specifically exclude the Internet would thus require a waiver of claim scope that is ‘both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer.’” (citing *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325–26 (Fed. Cir. 2003)). Additionally, the prosecution history supported a broader construction of “communications medium.” *Id.* At 1322-23.

Similarly, in *Northrop Grumman Corp. v. Intel Corp.*, 325 F.3d 1346 (Fed. Cir. 2003) (Chief Judge Mayer, Senior Circuit Judge Friedman, and Circuit Judge Bryson), Judge Bryson, writing for

the panel, disagreed with the district court and defendants that the specification's suggestion of broad application was mere "boilerplate." The district court in Northrop Grumman had construed the term "bus interface unit" to mean "a bus interface unit capable of functioning as a bus controller or a remote terminal when connected to a biphasic serial bus in a command/response system." According to the Federal Circuit, the district court's claim construction had been "dictated by the court's overall view of the patent as limited to use in a command/response system," and was "a more restrictive interpretation, consistent with the court's understanding of the objectives of the patent and the preferred embodiment." The Federal Circuit, in reviewing the patent disclosure, observed that "[i]t is no doubt true that the inventor conceived that the invention * * * would be used principally, if not exclusively, in a 'command/response' environment." However, the Federal Circuit stated, "statements from the description of the preferred embodiment, moreover, are just that — descriptions of a preferred embodiment that operates in a command/response system. Those statements do not indicate that the invention can be used only with a 'command/response' protocol. Absent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the patent is limited to that context." The Federal Circuit noted that although the patent "discusse[d] at length an embodiment that implements the MIL-STD-1553 protocol, it [went] on to teach that other embodiments of the invention need not utilize that protocol." The Federal Circuit concluded that the patent's statement that " 'the present invention may be made to conform to any one of a variety of data transfer algorithms,' " was not "mere 'boilerplate' suggestion of broad application," and that the patentee "provide[d] substantive, albeit general, support for that declared intention." The Federal Circuit noted the parties' agreement "that a person of ordinary skill in the art at the time the invention was made would have had knowledge of protocols or data transfer algorithms that did not operate in a bus controller/remote terminal environment or require an operating mode signal such as signal 160." The Federal Circuit recognized that its construction "result[ed] in according those claims substantial breadth, and that the breadth of the claims may raise questions as to their validity," but stated that "[a]ny question as to validity, however, is for the district court to address on remand, inasmuch as the only issue before us on this appeal is claim construction." *Id.* At 1354-56.

Here, the patentees' statement that the disclosure in the section entitled "Description of the Invention" was a preferred embodiment and "not intended to limit the invention," is not only

consistent with how SARP appears in the claims, but also consistent with how the patentees described both the prior art optimization methods and the disclosed “preferred embodiment.”

(b) “Background of the Invention”

In the section of the specification entitled “Description of the Prior Art,” the patentees noted the existence of a variety of optimization methods, including SARP. As noted above, in a section of the specification entitled “Description of the Prior Art,” the patentees explain that although various “shutters” and other apparatus could be used to “minimize portions of the structures being exposed to radiation,” “exposure to surrounding structures cannot be completely prevented.” Col. 2, line 22 to col. 3, line 5; col. 3, lines 6-7. Thus, “treatment plans are desired that are optimized to eradicate the tumor volume while minimizing the amounts of radiation delivered to the surrounding structures.” Col. 3, lines 9-12.

According to the patentees, there were “existing methods and apparatus for optimizing treatment plans [that] use a computer to rate possible plans based on score functions which simulate a physician’s assessment of a treatment plan.” Col. 3, lines 12-15. Those “existing methods and apparatus” were said to “utilize a computational method of establishing optimized treatment plans based on an objective cost function that attributes costs of radiation of various portions of both the tumor and surrounding tissues, or structures.” Col. 3, lines 17-21. One of those computational methods was SARP:

One such computational method is known in the art as simulated annealing. Existing simulated annealing methods utilize cost functions that consider the costs of under-exposure of tumor volumes relative to over-exposure of surrounding structures.

Col. 3, lines 21-25 (emphasis added).

The patentees further explained that “the cost functions used in existing methods do not account for the structure volumes as a whole, relying merely on costs related to discrete points within the structure, and further do not account for the relative importance of varying surrounding structure types.” Col. 3, lines 25-29. Because “[e]xisting cost functions utilized in the optimization of treatment plans do not account for such varying costs associated with the different types of structures,” the patentees stated, “[a]fter the treatment plan is optimized, the physician currently must evaluate each computed treatment plan for compliance with the desired treatment objective. If the computed treatment plan does not successfully meet the treatment objectives, the optimization

process is repeated until a treatment plan can be computed that meets the physician's treatment objectives for both the tumor volume and the surrounding structures." Col. 3, lines 41-48. Also, the patentees explained, "existing methods and apparatus do not allow the physician to utilize the familiar partial volume data associated with Cumulative Dose Volume Histogram ("CDVH") curves in establishing the desired dose distributions." In short, the patentees concluded:

Accordingly, prior to the development of the present invention, there has been no method or apparatus for conformal radiation therapy, for use with a radiation beam having a predetermined, constant beam intensity for treatment of a tumor which: are simple and economical to use; that has what is believed to be a high safety factor for patient safety; which computes an optimal treatment ID plan to meet conflicting, pre-determined, treatment objectives of a physician, accounting for objectives in both the target tumor volume and multiple structure types; and which utilizes partial volume data or the associated CDVH curves in establishing the desired dose distributions for each target tumor volume and tissue and structure types.

Therefore, the art has sought a method and apparatus for conformal radiation therapy, for use with a radiation beam having a predetermined, constant beam intensity for treatment of a tumor which: is simple and economical to use; that has what is believed to be a high safety factor for patient safety; which computes an optimal treatment plan to meet conflicting, pre-determined, treatment objectives of a physician, accounting for objectives in both the target tumor volume and multiple structure types; and which utilizes partial volume data or the associated CDVH curves in establishing the desired dose distributions for each target tumor volume and tissue and structure types.

Col. 3, lines 53-65. Again, such "existing methods and apparatus" included SARP. In other words, all of the computational methods, or at least their cost functions, known at the time for optimizing treatment plans, including SARP, were inadequate for the foregoing reasons.

(c) "Detailed Description of the Invention"

However, in the "Detailed Description of the Invention" section of the patent, the patentees also disclose SARP as the preferred optimization method. The patentees reiterate at the beginning of that section that SARP methods "are well known in the art to compute optimized radiation beam arrangements to meet objective parameters of a physician with regard to conflicting treatment objectives of a tumor volume and its surrounding structures. Existing SARP methods utilize systematic algorithms to calculate a proposed, optimized beam arrangement." Col. 8, lines 61-67. According to the patentees, the then-known – and apparently inadequate – SARP technique could satisfy the apparently unmet objective of, for example, "utiliz[ing] partial volume data or the

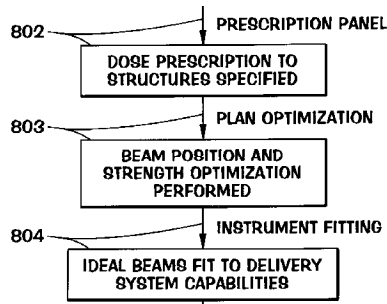
associated CDVH curves in establishing the desired dose distributions for each target tumor volume and tissue and structure types” if it used a different cost function. In particular, in the “Detailed Description of the Invention,” the patentees disclosed a cost function by which “each region, or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone, of the CDVH.” Col. 13, lines 4-7.

The specification makes that clear in a number of places. As noted above, the patentees disclosed in the “Detailed Description of the Invention” an “optimizer” said to “compute an optimized treatment plan, or beam arrangement” using SARP:

The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose. At each iteration, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures. If the increase or decrease in beam weights would lead to a greater correspondence to the desired prescription, the change is accepted. Ultimately, the SARP method will produce an optimized treatment plan, based on the treatment objectives as expressed by the cost function incorporated in the SARP algorithm.

Col. 9, lines 34-48 (emphasis added). The patentees also disclosed an “improved optimized treatment planning system” that “includes a modified cost function, which allows a physician to use conventional cumulative dose volume histograms (‘CDVH’s) to establish a desired prescription of dosage to both the target volume, or target, and each involved structure volume, or structure, which will then be used as input for the system for determining the proposed radiation dose distribution for delivery to a patient.” Col. 9, lines 52-59 (emphasis added). That “modified cost function” may apparently be provided in the “system” using “plan optimization software, which utilizes the optimization method of the present invention,” but the “system” otherwise uses “conventional equipment, including a conventional linear accelerator (‘LINAC’) 300, * * * having a rotatable gantry, a conventional computer or set of computers.” Col. 9, lines 59-64.

The patentees discuss SARP and the “modified cost function” in connection with “Plan Optimization Step 803” of Figure 2 (reproduced in part below), which is said to “show[] a procedure for creating a treatment plan utilizing the system of the present invention:”



In the preceding “Prescription Panel step 802,” the physician can “input into the planning system the desired goal of the radiation therapy treatment, which is utilized in the plan optimization step 803.” Col. 10, lines 31-34.

In “Plan Optimization Step 803,” the patentees provide more detail regarding how the “optimizer” determines the “optimal beam arrangement:”

In the Plan Optimization step 803, the radiation plan optimization is a specific case of an inverse problem, where the goal is to determine the best way to achieve the dose prescription. A SARP technique is utilized to do this optimization by dividing the radiation delivery into a large number of small beams, each of which hit the target. The annealing cooling schedule utilized, fits into the class of FSA (Fast Simulated Annealing) techniques. Except for the foregoing detailed description of the cost function utilized in the present system, the details of the foregoing simulated annealing techniques are known in the art and are described in such publications as “Optimization of Conformal Radiotherapy Dose Distributions by Simulated Annealing”, S. Webb, Physics and Medical Biology, Vol. 34, PP. 1349-1370 (1989); and “Optimization of Conformal Radiotherapy Dose Distributions by Simulated Annealing: 2. Inclusion of Scatter in the 2d Technique”, S. Webb, Physics and Medical Biology, vol. 36, pp. 1227-1237, (1991), which publications are incorporated herein by reference. A suitable computer is utilized in performing the Plan Optimization step, as well as the other steps of the radiation planning system.

Col. 12, lines 27-47 (emphasis added). The patentees do not further discuss SARP in connection with the “Plan Optimization step 803” (or in connection with any other step), but thereafter provide a “detailed description of the cost function utilized in the present invention.”

In the succeeding “Instrument Fitting step 804,” “[t]he resulting optimized set of radiation beam positions and beam weights, or beam intensities for the radiation beam segments, is fitted into the delivery capabilities of the LINAC apparatus 300 (FIG. 1), after optimization.” Col. 15, lines 47-52.

According to the patentees, therefore, a new cost function could be used with known equipment and at least one known optimization technique, SARP, to allow use of CDVH and partial volume data in the optimization planning process.

(d) SARP and the Disclosed “cost function”

In view of the foregoing, Accuray is by and large correct that the ‘283 patent generally discloses a “modified cost function” as new, and uses that “modified cost function” in connection with a known optimization method, SARP. But Accuray further urges that the disclosed cost function cannot be used with other optimization methods – at least not without “significant experimentation by those of skill in the art.” But that is a question of enablement which, as noted above, involves a different standard of proof, *i.e.*, clear and convincing, as well as a different question, *i.e.* whether the specification teaches those skilled in the art how to make and use the full scope of the claimed invention without “undue experimentation” (as opposed to Accuray’s representation “significant experimentation,” which is not the standard) that in turn requires resolving what constitutes “undue experimentation,” that likewise, in turn, depends on considering a number of factors, namely: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Wands*, 858 F.2d at 737. The current record contains virtually no basis for evaluating those factors.

Immediately after describing the formulas and variable of the cost function, the patentees indicate that the “cost function” could be used with “conventional optimization techniques,” not just with SARP:

In other words, if the region under the proposed CDVH curve, or pseudo-curve, is greater than the region under the desired CDVH curve, there is a high cost associated with the change to the proposed beam distribution. Thus, the system will reject the change that was made to the beams and will again attempt to change the beam weights to lower the total cost, according to conventional optimization techniques known in the art. Where target goals and structure limits conflict, beam changes will decrease the

cost in the target while increasing the cost in one or more of the structures. A determination of whether or not that beam change is kept by the system depends upon the relative changes in the costs of the targets and structures.

Col. 13, lines 40-52 (emphasis added). That is consistent with the patentees' discussion of prior art optimization methods, and in particular with their inadequate cost functions. Again, according to the patentees, "[e]xisting cost functions utilized in the optimization of treatment plans do not account for such varying costs associated with the different types of structures." That is, the cost functions of the "conventional" optimization methods were inadequate, not necessarily those optimization methods *per se*. Thus, the patentees disclosed a "modified cost function" said to account for those varying costs.

As noted above, use of that "modified cost function" allowed physicians to use the "well known" SARP for optimization where use of SARP would have – according to the patentees – previously been unable to account for such costs. According to the specification, that could be "easily" accomplished by one skilled in the art. Col. 15, lines 44-46 ("The cost function of the present invention may be easily incorporated into existing SARP algorithms by one skilled in the art."). Here, the patentees indicate that other "conventional optimization techniques" could similarly account for such costs by incorporating the disclosed "cost function." Unlike with SARP, the patentees do not state that such incorporation may be easily accomplished by an artisan. Nevertheless, the patentees' indication that the disclosed cost function could be used with other optimization techniques supports viewing the patentees' statement that the disclosed subject matter was a "preferred embodiment" as more than mere "boilerplate." The patentees' discussion of the apparent inadequacies of known optimization methods (including SARP), and indication that the disclosed cost function could be used not only with SARP, but also with other known optimization methods, substantiates that statement.

It is true that the patentees do not identify those “conventional optimization techniques” by name. Nevertheless, the parties do not dispute the existence of a number of optimization methods at the time of filing. Indeed, both parties identify several optimization methods that existed at the time of filing of the ‘283 patent. Accuray’s tutorial provided during the *Markman* Hearing included the following:

Treatment Plan Optimization

- By mid-1990’s, optimization algorithms that had been studied included:
 - exhaustive search
 - linear programming
 - quadratic programming
 - mixed-integer programming
 - downhill simplex
 - feasibility solutions
 - simulated annealing
 - etc.

Accuray’s Technology Tutorial Slides at 75.

Similarly, Best Medical’s tutorial during the *Markman* Hearing included the following:



Best Medical’s Technology Tutorial Slides at 47. *See also Markman* Tr. at 23-24. It may be, as Accuray urges, that none of those known optimization methods could be used with the “modified cost function” disclosed in the ‘283 patent without “significant experimentation.” However, to the extent that Accuray urges that failure to limit claim 25 to use of SARP would invalidate that claim

for lack of enablement, the court cannot – as noted above – rewrite claim 25 to “save” it from invalidity. *See E.I. du Pont de Nemours*, 849 F.3d at 1434. Resolution of that issue goes beyond the scope of claim construction. Consistent with the Court’s decision regarding Accuray’s arguments regarding invalidity of Claim 29 at the *Markman* Hearing, such invalidity arguments should be briefed separately. *See Markman* Tr. at 157. Again, the issue of whether the specification satisfies the requirement of teaching those having skill in the art how to make and use the full scope of the claimed invention, turns on whether they can do so without “undue experimentation,” and requires a different standard of proof. That evaluation depends on a number of factors. *See In re Wands*, 858 F.2d at 737. Such evaluation is beyond the scope of this report and recommendation.

(e) “Summary of the Invention”

The rest of the specification confirms that claim 25 is not limited to SARP. In the section of the specification entitled “Summary of the Invention,” the patentees explain that “[i]n accordance with the invention, the foregoing advantages have been achieved through” several methods and apparatus. Some of those methods and apparatus require SARP; some do not. For example, the first method essentially includes the steps of claim 1:

using a computer to computationally obtain a proposed radiation beam arrangement;

using a computer to computationally change the proposed radiation beam arrangement iteratively, incorporating a cost function at each iteration to approach correspondence of a CDVH associated with the proposed radiation beam arrangement to a CDVH associated with a pre-determined desired dose prescription; and

rejecting the change of the proposed beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired prescription to obtain an optimized radiation beam arrangement.

Col. 4, lines 13-33. That method does not expressly call for using SARP. However, after explaining in detail how the cost function may be obtained through various steps and formulae, the “Summary of the Invention” states that SARP may be used: “Further, the optimized radiation beam arrangement may be applied to the patient with a conformal radiation therapy apparatus and the proposed radiation beam arrangement may be calculated using simulated annealing radiation therapy planning methods.” Col. 4, line 66–col. 5, line 3 (emphasis added). The patentees’ terminology suggests that use of SARP is optional, *i.e.*, not required for performing the method. *See PSN Illinois*,

LLC v. Ivoclar Vivadent, Inc., 525 F.3d 1159, 1165-66 (Fed. Cir. 2008) (patentee's use of the term "may" indicated that the described feature was optional). That is consistent with the differences among the claims of the '283 patent, and also consistent with how the patentees disclosed the preferred embodiment.

The remainder of the "Summary of the Invention" similarly states that SARP "may" be used to calculate the "proposed radiation beam arrangement" or "optimized radiation beam arrangement," as shown below:

- "Further, the proposed radiation beam arrangement may be calculated using simulated annealing radiation therapy planning methods and the optimized radiation beam arrangement may be applied to the patient using a conformal radiation therapy apparatus." Col. 5, lines 43-47 (emphasis added).
- "Still further, the proposed radiation beam arrangement may be calculated using simulated annealing radiation therapy planning methods." Col. 6, lines 20-22 (emphasis added).
- "Still further, the optimized radiation beam arrangement may be calculated using simulated annealing radiation therapy planning methods, the optimized radiation beam arrangement may be applied to the patient with a conformal radiation therapy apparatus, and the desired CDVHs may be computationally constructed by the computer based on numerical values representing the partial volume data entered into the computer." Col. 7, lines 58-65 (emphasis added).

(f) Abstract

Also, the Abstract of the '283 patent generally describes "[a] method and apparatus" which determines an optimized radiation beam arrangement:

A method and apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, which uses an iterative cost function based on a comparison of desired partial volume data, which may be represented by cumulative dose volume histograms and proposed partial volume data, which may be represented by cumulative dose volume histograms for target tumors and tissue structures for delivery of the optimized radiation beam arrangement to the patient by a conformal radiation therapy apparatus.

The patentees do not describe SARP as the "method" for "determining an optimized beam arrangement." See *Hill-Rom Co. v. Kinetic Concepts*, 209 F.3d 1337, 1341 n.1 (Fed. Cir. 2000) ("We have frequently looked to the abstract to determine the scope of the invention, and we are aware of

no legal principle that would require us to disregard that potentially helpful source of intrinsic evidence as to the meaning of claims.” (citations omitted)). In the Abstract, as well, the patentees focused on “an iterative cost function,” not on SARP.

In sum, the specification contains no “intentional disclaimer, or disavowal, of claim scope,” or otherwise limits claim 25 to use of SARP.

(4) Prosecution History

“Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent.” *Phillips*, 415 F.3d at 1317. “[A]n applicant can make a binding disavowal of claim scope in the course of prosecuting the patent, through arguments made to distinguish prior art references. Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter.” *Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008). One reason for the “clear and unmistakable surrender” standard is that “because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Phillips*, 415 F.3d at 1317. “Nonetheless,” the Federal Circuit explains, “the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

Here, though, the prosecution history does not show that the patentees limited claim 25 to SARP or “clearly disavowed” use of other optimization methods. In an office action dated February 16, 1999, the examiner rejected claim 25 (originally claims 26 and 27) as anticipated by Patent No. 5,513,238 (“Leber”) under 35 U.S.C. § 102(e). The examiner stated that “Leber shows all of the features of the instant invention including radiation (therapy) beam optimization to a target volume and minimizing radiation to a structure volume, using a computer to modify the beam arrangement, and rejecting the new arrangement if it has a lesser correspondence to the desired radiation prescription (column 4 line 5 – column 6 line 2).” JCC, Exh. 2, at 2.

The applicants responded by adding the limitation “wherein the proposed radiation arrangement is changed by changing the beam weights” to claim 25 and other claims. Substantively, the applicants noted that the prior art disclosed a “method for optimization of radiation therapy planning:”

U.S. Patent No. 5,602,892, to Leber et al. discloses a method for optimization of radiation therapy planning, including a method and apparatus for solving a numerical optimization problem that yields pencil beam fluences that will result in the optimum treatment plan using a predetermined set of gantry angles and a set of selected pencil beams for each of those gantry angles. The preferred method and apparatus for solving the numerical optimization problem comprises a computer running a new Dynamically Penalized Likelihood (DPL) iterative algorithm (Col. 3., II. 59-67, Col. 4., line 1).

JCC, Exh. 3, at 5.

As Best Medical argues, there is no indication that the patentees or the examiner understood claim 25 to be limited to SARP, nor did the patentees rely on SARP to distinguish the prior art. As Accuray notes, although the patentees referred to Leber in their argument, the substance of their argument actually referred to the DPL algorithm disclosed in U.S. Patent 5,602,892 to Llacer, which had been made of record by the examiner as “show[ing] a system similar to Leber et. al.” JCC, Exh. 2 at 3.⁴ Regardless, the patentees’ arguments to the examiner do not constitute a “clear and unmistakable” surrender of other optimization methods, or otherwise limit claim 25 to SARP.

⁴ Although the applicants referred to Leber in their argument, their argument actually referred to the disclosure of Llacer.

A method for optimization of radiation therapy planning based on a new Dynamically Penalized Likelihood (DLP) [sic] algorithm. The target function of the DLP algorithm contains likelihood terms and penalty terms connected to the likelihood terms by a number of dynamically updated penalty coefficients. The method results in a highly uniform dose to the tumor or radiosurgery volume, at the expense of some non-uniformity in the dose delivered to defined sensitive tissues.

The column/lines identified by applicants in their argument, if applied to Leber, do not reveal any discussion of DPL, nor does Leber discuss DPL.

(5) Extrinsic Evidence

In construing claims, courts may “rely on extrinsic evidence, which ‘consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.’” *Phillips*, 415 F.3d at 1317 (quoting *Markman*, 52 F.2d at 980). However, extrinsic evidence is generally “less reliable than the patent and its prosecution history in determining how to read claim terms, for several reasons:”

- “First, extrinsic evidence by definition is not part of the patent and does not have the specification’s virtue of being created at the time of patent prosecution for the purpose of explaining the patent’s scope and meaning.”
- “Second, while claims are construed as they would be understood by a hypothetical person of skill in the art, extrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent.”
- “Third, extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.”
- “Fourth, there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question.”
- “Finally, undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the ‘indisputable public

However, those column/lines as applied to Llacer do disclose of DPL:

Specifically the invention includes a method and apparatus for solving a numerical optimization problem that yields the pencil beam fluences that will result in the optimum treatment plan using a predetermined set of gantry angles and a set of selected pencil beams for each of those gantry angles.

The preferred method and apparatus for solving the numerical optimization problem comprises a computer running a new Dynamically Penalized Likelihood (DPL) iterative algorithm.

Llacer, col. 3, line 57 to col. 4, line 1. The applicants did not otherwise substantively discuss Leber or Llacer.

records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents."

Phillips, 415 F.3d 1318-19.

Accuray relies on the testimony of its expert, Dr. Rosen, in urging that claim 25 should be limited to SARP. According to Dr. Rosen: "I have been asked to opine about the technology at issue in the '283 patent." Rosen Decl., ¶ 12. With respect to each of Accuray's proposed constructions, Dr. Rosen states: "I agree with Accuray's construction, and it is my opinion that one skilled in the art would interpret this phrase in this way, in view of the specification, the file history and the general knowledge of those skilled in the art at the time the '283 patent was filed." Rosen Decl., ¶¶ 21-27. Dr. Rosen states that "[t]he bases for my opinions herein and any testimony that I may be called upon to give are the materials identified throughout my Declaration and Exhibit 3, my education, my vast experience, as well as the materials listed in my declaration and/or submitted by the Parties in their Joint Disputed Claim Terms Chart pursuant to Local Patent Rule 4.2." *Id.*, ¶ 29.

With respect to claims 25 and 29, Dr. Rosen opines as follows:

115. Claims 25 and 29 of the '238 patent are directed to a computer that runs a simulated annealing algorithm to determine an optimized radiation treatment plan for delivery to the patient. Claims 25 and 29 of the '283 patent are directed specifically to the optimization of beam weights. The claims do not address optimization of beam geometry.

116. Beam weights, although related to dose, are not equivalent to dose. Beam weight, or beam intensity, refers to the radiation that is emitted from beamlets of a beam at the source, the linear accelerator (as discussed above). Dose, on the other hand, refers to the radiation that is absorbed by the tissue.

117. The patent describes existing methods for delivering conformal treatments. It does not claim a new conformal radiation therapy apparatus.

118. In the "SUMMARY OF INVENTION", the patent describes a methodology to be implemented on a computer for determining the optimum intensity maps for an IMRT treatment. It further states that the resulting optimized radiation beam arrangement should be capable of delivery with a conformal radiation therapy apparatus [C8, L14].

119. One skilled in the art at the time that the '283 patent was filed would understand that, in order to computationally obtain a proposed array of beam weights, a computer would have to be configured with and run treatment planning optimization software, including a specific optimization algorithm.

120. There are essentially three components to the inverse planning method presented in the patent: the computer configured to run an optimization

algorithm for finding the optimum beam weights [e.g., C7, L11-L25], the method of user definition of the treatment planning goals [e.g., Figure 5, C10, L53 - C11, L8], and the cost function that mathematically describes the goal of optimization [e.g., C13, L10-39, Figure 3 and 4].

121. Dr. Webb's 1989 article, incorporated by reference in the specification of the '283 patent, explains that the simulated annealing algorithm is used to obtain a proposed set of beam weights. The specification of the '283 patent does not describe how the proposed set of beam weight is obtained, other than by reference to Dr. Webb's articles. [Webb 1989]

122. Neither the '283 patent specification nor Dr. Webb's articles disclose any way to obtain a proposed set of beam weights for IMRT other than through simulated annealing.

123. The use of simulated annealing to calculate a proposed radiation beam arrangement was well known in the art prior to the time of the patent filing, and the patent acknowledges that [C8, L61]. At each iteration of the simulated annealing algorithm, a new proposed set of beam weights is obtained by randomly adding or subtracting small grains (or amounts) of beam weight. [Webb 1989] By changing the beam weights at a particular iteration, a new proposed radiation beam arrangement or new set or array of beam weights is created. The change of beam weights at a particular iteration results in a new proposed radiation beam arrangement, which is the new proposed solution for that iteration. The concept of proposing a new solution at each iteration is consistent with optimization algorithms such as simulated annealing.

124. One skilled in the art would have understood that the cost function claimed in the '283 patent is the specific cost function described in Column 13, in light of the specification, the Webb articles, and knowledge and experience in the field. One skilled in the art would not have understood the claimed cost function to encompass any cost function, because it was well known that a variety of cost functions had been used with variants of the simulated annealing algorithm (and with other algorithms) to optimize beam weights prior to the filing date of the '283 application.

125. The specific cost function described in Column 13 of the '283 patent was a non-linear cost function and was designed to solve a particular problem. The cost function is non-linear because it incorporates partial volume data or CDVH parameters into the cost function.

126. The specification teaches that the cost function of the '283 patent is incorporated into the simulated annealing algorithm. The specification does not teach how to use this cost function with any optimization algorithm other than simulated annealing.

127. In my opinion, one of ordinary skill in the art at that time would have appreciated that it would have required additional experimentation for one skilled in the art to determine how to use the cost function of the '283 patent with an algorithm other than simulated annealing. Indeed, it would not have

been a trivial exercise to attempt to use an algorithm other than simulated annealing with this cost function.

128. Given that there is no disclosure of any optimization algorithm other than simulated annealing (and its variants, such as fast simulated annealing) in the '283 patent or the Webb articles, and that it would have been difficult to figure out a way to use the cost function of the '283 patent with any algorithm other than simulated annealing, one skilled in the art would understand that claims 25 and 29 are limited to a computer that runs a simulated annealing algorithm. Moreover, one of skill in the art would recognize that a stochastic algorithm such as simulated annealing would be required with such a cost function.

129. In a publication contemporaneous with the filing of the '283 patent, Dr. Carol explained the meaning of the phrase "changing the proposed radiation beam arrangement iteratively." Dr. Carol explained: "The iterative approach to solving the optimization problem involves iteratively changing the strengths of the individual beamlets until a satisfactory solution is achieved." [Carol 1997C, p. 317]

130. In my opinion, the skilled artisan at the time the '283 patent application was filed would have appreciated that the "partial volume data associated with the predetermined desired dose prescription" referred to the partial volume data for each target and structure entered into the prescription panel by the user before the optimization, based on the desired dose prescription of the physician. Such partial volume data were used to generate a CDVH curve for each target and structure that represented the desired dose prescribed by the physician.

131. The skilled artisan would have appreciated that the total cost of the claimed cost function could not be calculated without referring to the CDVH's because the cost functions depend on the zones of the CDVH curves, and the weighting factors for each of the zones.

132. The skilled artisan would have appreciated that the cost function compares the CDVH associated with the predetermined desired dose prescription with the CDVH's associated with the proposed radiation beam arrangement at each iteration of the simulated annealing algorithm and calculates a cost.

133. The cost function calculates the total cost of the proposed array of beam weights at a particular iteration of the simulated annealing algorithm based on the formulas disclosed in Column 13 of the '283 patent. This number itself does not mean much; it is an abstract concept and does not indicate whether the proposed solution is a good solution. Only by comparing the total cost of proposed beam weight solution of the given iteration to the cost of the proposed beam weight solution of the previous iteration, can one tell whether the solution is better or worse. This comparison of costs is implicit in the terms "greater correspondence" or "lesser correspondence" found in the last "accept or reject" limitation of the asserted claims.

134. One skilled in the art at the time the '283 patent was filed would understand that the simulated annealing algorithm would reject the new proposed array of beam weights if the total cost was higher than the total cost of

the accepted proposed solution of the previous iteration, and would accept the new proposed array of beam weights if the total cost was lower than the total cost of the accepted proposed solution of the previous iteration. Practically speaking, the comparison must be between the proposed solution of the current iteration and the last accepted solution of a previous iteration. If the solution of the immediately preceding iteration was rejected, it would not have been available as a comparator.

Rosen Decl., ¶¶ 115-134.

With respect to whether claim 25 is limited to SARP, Dr. Rosen's opinion is based on (1) the specification's lack of disclosure of any optimization algorithm other than SARP, and (2) the "additional experimentation" required to use the disclosed cost function with any other optimization algorithm than SARP. Rosen Decl., ¶¶ 127-128. Expert testimony can, of course, "be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. However, the Federal Circuit counsels that "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'" *Id.* at 1319. *See also Kara*, 582 F.3d at 1348 (while helpful, extrinsic sources like expert testimony cannot overcome more persuasive intrinsic evidence."). As discussed above, the intrinsic record, namely, the claims, specification and prosecution history, all indicate that claim 25 is not limited to SARP. The fact that the '283 patent only discloses SARP does not require a conclusion otherwise, and Dr. Rosen's testimony, essentially saying what is already evident, offers nothing in addition. Nor does Dr. Rosen's "additional experimentation" rationale require limiting claim 25 to SARP. Once again, that testimony pertains to issues of validity under § 112, and such issues are beyond the scope of this report and recommendation.

(6) Conclusion

Claim 25, while clearly drawn to iterative optimization methods, is not expressly limited to simulated annealing. The specification consistently describes simulated annealing as one optimization method among others, and as the preferred embodiment. The specification further

indicates that the disclosed cost function may be used with “conventional optimization techniques,” not just with SARP. The prosecution history does not clearly disclaim or disavow use of other optimization methods.

As of October 24, 1996, the earliest priority date for the patent-in-suit, there were a number of optimization methods in use for conformal radiation therapy. SARP was just one optimization algorithm of many known at the time the ‘283 patent was filed, as the parties agree. Accuray’s arguments that Best Medical’s construction would lead to invalidity of the ‘283 patent, *e.g.*, because the disclosed cost function could not be used with those other known optimization algorithms without undue experimentation, carry a different burden of proof as well as a consideration of different factors, none of which are mutually or fully addressed by the parties, and are beyond the scope of this report and recommendation. Again, consistent with the Court’s decision regarding alleged invalidity of Claim 29 at the *Markman* Hearing, such invalidity arguments should be briefed separately. *See Markman* Tr. at 157.

c) Recommendation

In view of the foregoing, therefore, the master recommends that the Court conclude that asserted claim 25 is not limited to optimization by simulated annealing, or SARP.

3. Whether the term “cost function” is limited to the cost function described in the ‘283 Patent

The second overarching dispute between the parties is whether the term “cost function” is limited to the cost function described in the ‘283 patent at column 13, lines 4-39. *See Markman* Tr. at 142.

The term “cost function” appears in claim 25 as shown below (emphasis added):

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, * * *

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the

proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and * * *

a) The Parties' Proposed Constructions and Arguments

The parties originally proposed the following constructions for the claim term “cost function:”

<u>BEST MEDICAL</u>	<u>ACCURAY</u>
An analytical determination of whether, when any change is made to the strength of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user.	<p>The cost function of the present invention is explicitly defined at col. 13, lines 4-39, including each of the steps described therein:</p> <p>In the cost function of the present invention, each region, or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone, of the CDVH. A zone cost is then calculated for the target and each structure, according to the following formula: $C_z = W_z * (A_p / A_d)$,</p> <p>After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula: $C_T = \Sigma C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}$, and $C_S = \Sigma C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}$,</p> <p>The total cost for the change to the proposed beam distribution is then calculated, according to the following formula:</p> $C_{Total} = C_S + C_T,$ <p>where C_{Total} is the total cost of the proposed change to the beam distribution.</p>

See JCC, at 36-43.

Best Medical argues that “cost function” is defined in the specification of the ‘283 patent, citing column 13, line 1-4 of the ‘283 patent:

The cost function is an analytical determination of whether, when any change is made to the strengths of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user.

Best Medical’s Reply at 16, 22. Best Medical contends that Accuray “ignores this definition and attempts to incorporate the equations used in the preferred embodiment.” *Id.* at 16. Best Medical also argues that “Accuray attempts to improperly read such limitations into this basic phrase by

incorporating CDVH curves into the claim. As with the SARP algorithm, the CDVH curves are described as a non-limiting embodiment of the invention, and are recited elsewhere in non-asserted dependent Claims 2, 10-13, 24, 26, 28, 30, 32, 37, 39, 41, 44 and 47.” *Id.* at 17.

Accuray responds that “[b]y [the ‘283 patent’s] consistent references to the specific cost function disclosed in Column 13 as the ‘cost function of the present invention,’ the specification confirms Accuray’s construction.” Accuray’s Response at 35. Column 13 at lines 4-39, discloses the following:

In the cost function of the present invention, each region, or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone, of the CDVH. A zone cost is then calculated for the target and each structure, according to the following formula:

$$C_z = W_z * (A_p / A_d),$$

where C_z is the cost for the current zone, W_z is the weight assigned to the current zone, A_p is the area of the current zone of the proposed CDVH curve, or pseudo-curve, and where A_d is the area of the current zone of the desired CDVH curve except for target zone T7, where A_d is the length represented by target zone T7 and structure zone S8, where A_d is the length represented by structure zone S8. After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula:

$$C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}, \text{ and}$$

$$C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$$

where C_S and C_T are the cost for each structure or zone, and C_{z1} , C_{z2} , C_{z3} , and C_{zn} are the costs calculated for each zone of the first, second, and third, through n th zone of each target or structure. The total cost for the change to the proposed beam distribution is then calculated, according to the following formula:

$$C_{\text{Total}} = C_S + C_T,$$

where C_{Total} is the total cost of the proposed change to the beam distribution.

Accuray cites to the following portions of the specification of the ‘283 patent to further support its contention:

In the cost function of the present invention, each region, or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone, of the CDVH.

Col. 13, lines 4-7;

A selection of 3 would then bias the system toward treating the target volume while a selection of 7 would bias the system toward preserving the surrounding structures. The cost function of the present invention may be easily incorporated into existing SARP algorithms by one skilled in the art.

Col. 15, lines 41-46;

Except for the foregoing detailed description of the cost function utilized in the present system, the details of the foregoing simulated annealing techniques are known in the art and are described in [Webb (1989) and Webb (1991)].

Col. 12, lines 34-45.

In addition, Accuray argues that “[n]o other cost function (and no other optimization algorithm) is disclosed in the specification.” Accuray’s Response at 35. Accuray contends that “the specification repeatedly refers to the specific cost function disclosed at column 13 as the only aspect of the disclosure that is not known in the art.” *Id.* Accuray also contends that “[a]s clearly stated in the specification, the improvement, if any, in the ‘283 patent, is the addition of a modified cost function incorporated into the well-known simulated annealing algorithm. Support for this construction is also found in the specification’s explanation of the problem with prior art cost functions used with simulated annealing to determine optimized beam weights. The specification purportedly provides a solution with the ‘modified’ cost function disclosed in Column 13.” *Id.* at 36 (citations omitted).

Accuray urges that “[t]he only detailed disclosure found in the specification is that of the ‘modified’ cost function and the specific input parameters for that cost function (the partial volume data used to generate CDVH curves for each target and structure, those CDVH curves divided into zones, and the differential weighting factors for those zones depending on the user’s desired outcome),” and that “[t]he specification consistently refers to the specific cost function disclosed in Column 13 as ‘the present invention.’” *Id.* at 36, 44.

Relying on the declaration of its expert, Dr. Rosen, Accuray also urges that “[o]ne of ordinary skill in the art at the time would have understood the cost function claimed in the patent is the specific cost function disclosed at column 13.” *Id.* at 40. Accuray also argues that “[o]ne of skill in the art would not have understood this term to mean any cost function because a variety of cost functions had been used with variants of the simulated annealing algorithm (and other algorithms) to optimize beam weights. Indeed, ‘The power of simulated annealing lies in the potentially infinite flexibility of choice of cost functions.’ And the ‘computation of the cost function is at the heart of the iterative solution.’ Thus, at best, **only** the particular cost function disclosed at column 13, using the specific input parameters of partial volume data, CDVHs, zones, and weighting of zones, could have been a contribution to the art.” *Id.* at 40 (citations omitted, Accuray’s emphasis).

According to Accuray:

one of skill in the art would have appreciated that the cost function disclosed in column 13 was a non-linear cost function with multiple potential solutions (local minima), and that a stochastic algorithm like simulated annealing, which searches the solution space randomly, was the best algorithm to use with it. One of skill in the art would have known that Dr. Carol had prior experience with simulated annealing and in particular, FSA, and had used it in the unpatented, precursor Peacock planning system, and that simulated annealing is especially useful with complex cost functions, and in particular, complex nonlinear cost functions that used CDVH (multiple partial volume data variables). One of skill in the art also would have appreciated that at the time of filing of the application, this non-linear cost function could not be used with other optimization algorithms without significant experimentation by those of skill in the art.

Id. at 41.

Accuray argues that “[t]he cost function cannot be construed to be any broader than the specific disclosure in col. 13. The specification consistently refers to the specific cost function disclosed in Column 13 as ‘the present invention,’ and indicates that only the cost function was new. Moreover, various cost functions had previously been incorporated into variants of the simulated annealing algorithm and used to optimize beam weights. Dr. Carol himself had used the Fast Simulated Annealing algorithm with a form of Dr. Webb’s cost function in the precursor Peacock system. Thus [Best Medical’s] construction, which would include any cost function, cannot possibly be correct.” *Id.* at 44.

Accuray also contends that Best Medical “concedes for claim 29 that the claimed cost function is the specific cost function disclosed in Column 13, yet ignores that disclosure in construing the cost function of Claim 25.” *Id.* Accuray also urges that “[Best Medical’s] construction flies in the face of the intrinsic and extrinsic evidence, and would render the claim invalid for anticipation over a myriad of prior art references, including the inventor’s own precursor Peacock system and the Webb references purportedly incorporated by reference in the specification. Assuming, arguendo, both constructions are conceivable, it defies belief that the Examiner would have allowed the claims with that interpretation.” *Id.* (citations omitted).

In reply, Best Medical again urges that “Accuray invites the Court to import a limitation from the specification into the claim.” Best Medical’s Reply at 21. Best Medical also states that “Accuray argues that ‘a cost function’ includes ‘each of the steps described’ in Col. 13:4-39 * * * which is an attempt to impermissibly narrow the scope of Claim 25 by reading into the claim several features that do not appear in the claim language.” *Id.* Best Medical argues that

“Accuray’s proposed construction disregards the ordinary and customary meaning of the term, and re-writes the claim using the litigation-generated Rosen Declaration.” *Id.* Best Medical argues that “[t]he specification clearly defines the term ‘cost function’: ‘The cost function is an analytical determination of whether, when any change is made to the strengths of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user.’ Since the ‘cost function’ is specifically defined in the specification, it requires no further construction.” *Id.* at 22 (emphasis added).

Accuray responds by reiterating that “the specification repeatedly refers to the ‘cost function of the present invention’ as the specific cost function disclosed in column 13.” Accuray’s Sur-Reply at 34. Accuray also states that “the patentee concedes that everything in the patent is known in the art except the specific cost function. [Best Medical] provides no specific response to Accuray’s arguments, relying only on ‘ordinary meaning’ and column 13:1-4 to support its construction.” *Id.* Accuray argues that Best Medical’s “construction of ‘cost function’ as any cost function cannot possibly be correct because it would render the ‘283 patent invalid over the Webb articles incorporated by reference and every other prior art reference that discloses treatment planning optimization.” *Id.* at 34-35.

Accuray also argues that “[t]he explicit definition of cost function includes column 13:4-39, which starts off with the phrase, ‘In the cost function of the present invention,’ and then goes on to describe the specific formulas. Nothing could be clearer.” *Id.* at 35.

b) Discussion

Here, as well, Accuray contends that the specification requires that the term “cost function” be construed to include the formulas and variables of column 13 of the specification. Accuray’s arguments reduce to: (1) “the patentee concedes [*sic*] that everything in the patent is known in the art except the specific cost function,” (2) construing “cost function” according to its ordinary meaning “would render the ‘283 patent is [*sic*] invalid over the Webb articles incorporated by reference and every other prior art reference that discloses treatment planning optimization,” and (3) the specification uses the words “the present invention” in connection with the disclosed cost function. Accuray’s Sur-Reply, at 34-35. Accuray also notes that “[n]o other cost function * * * is disclosed in the specification.” Accuray’s Response, at 35. Accuray does not argue that the cost function as set forth in column 13, lines 4-39, provides the “ordinary and customary meaning,” *i.e.*, “the term would

have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1312-13 (citations omitted).

(1) Claim Language

(a) Ordinary and Customary Meaning

As before, the analysis begins with the language of claim 25. *See Markman*, 52 F.3d at 980; *Phillips*, 415 F.3d at 1314. The plain language of claim 25 simply requires “a cost function:”

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

Claim 25 does not recite the equations or variables mentioned in column 13, lines 4-39. Claim 25 requires that the cost function use various “partial volume data,” but does not otherwise specify any particular cost function.

On its face, therefore, claim 25 is not limited to the cost function of column 13. Indeed, as with SARP, Accuray’s arguments regarding the technology indicates that the language of claim 25 was well-known and understood by persons of ordinary skill in the art – including the claim term “cost function.”

(b) Accuray's Description of the Technology

As noted in part above, Accuray urges, in reliance on Dr. Rosen, that the technology at issue with respect to cost functions and optimization algorithms involved the following:

- “Every optimization problem must have a goal.”
- “A ‘cost’ function is the mathematical description of that goal.”
- “Every potential solution to the problem has an associated cost, which is calculated by the cost function. Typically, algorithms attempt to minimize that cost.”
- “Some algorithms are limited in what cost functions they can optimize, and some algorithms are more efficient for a particular cost function than others.”
- “A variety of cost functions had been used in radiation therapy treatment plan optimization before the filing date.”
- “Early cost functions were simple mathematical functions, such as the maximum dose to the tumor that could be easily solved using analytic or deterministic methods.”
- “If the relationship can be written as an equation with the value of the cost on one side and the variables on the other side, then the cost function is said to be ‘analytic.’ Otherwise, the cost function is ‘non-analytic.’ Many optimization methods, such as linear programming methods, will not work with non-analytic cost functions.”
- “In a linear cost function, there is a linear relationship between the cost and the variables. In contrast, in a non-linear cost function, the cost does not have a linear relationship with the variables. When the cost function is non-linear, it is susceptible to local minima (or multiple solutions) within the solution space and requires a certain type of optimization algorithm to solve the problem. Stochastic algorithms, such as simulated annealing, are used to solve these problems because they are designed to escape local minima and find the global minimum (global solution).”
- “An example of a non-linear cost function is one that uses dose volume variables such as CDVH curves or the partial volume data from CDVH curves. * * * More clinically relevant cost functions based on CDVH’s require stochastic methods such as simulated annealing.”

Accuray’s Response at 6-8 (citations omitted).

Accuray concedes that there were at the time of filing a number of mathematically-described optimization goals generally known as “cost functions,” and that those cost functions did not necessarily include the formulas and variables described in column 13. Some cost functions were

apparently more useful than others for particular types of optimization algorithms, but the “ordinary and customary meaning” of the term “cost function” nevertheless connoted a wide variety of mathematical functions used for optimization, not just the mathematical function of column 13.

(c) Other Claims of the ‘283 Patent

Analysis of other claims suggests that “cost function” is not limited to the cost function described in column 13, lines 4-39. As noted above, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term.” *Phillips*, 415 F.3d 1314.

The term “cost function” is used in several other independent claims, namely, claims 1, 22, 29 and 36. Those independent claims use the term “cost function” in much the same way as does claim 25, *i.e.*, without reference to the formulas and variables of column 13. Claim 1 compares to claim 25 as follows:

<p>1. A method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising the steps of:</p> <p>using a computer to computationally obtain a proposed radiation beam arrangement;</p> <p>using a computer to computationally change the proposed radiation beam arrangement iteratively,</p> <p>incorporating a <u>cost function</u> at each iteration to approach correspondence of a CDVH associated with the proposed radiation beam arrangement to a CDVH associated with a predetermined desired dose prescription; and</p>	<p>25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:</p> <p>a computer, adapted to computationally obtain a proposed radiation beam arrangement,</p> <p>the computer further adapted to computationally change the proposed radiation beam arrangement iteratively,</p> <p>wherein the proposed radiation beam arrangement is changed by changing the beam weights,</p> <p>the computer further adapted to incorporate a <u>cost function</u> at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and</p>
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rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired prescription and accepting the change of the proposed beam arrangement if the change of the proposed beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

Claim 22 compares to claim 25 as follows:

22. A method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising the steps of:

using a computer to computationally obtain a proposed radiation beam arrangement;

using a computer to computationally change the proposed radiation beam arrangement iteratively,

incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription,

wherein the proposed radiation beam arrangement is changed by changing the beam weights; and

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively,

wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and

rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired prescription to obtain an optimized radiation beam arrangement.

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

Claim 29, which is asserted in this case, is an apparatus claim like claim 25, but couched in means-plus-function language:

29. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising a computer, including:

means for computationally obtaining a proposed radiation beam arrangement

means for computationally changing the proposed radiation beam arrangement iteratively, wherein the means for computationally changing the proposed radiation beam arrangement includes a means for changing the beam weights;

means for incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription; and

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and

means for rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

Finally, claim 36 compares to claim 25 as follows:

36. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement;

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

None of those other independent claims require the formulas or variables of column 13. Rather, they use the term “cost function” much as does claim 25.

Various dependent claims further indicate that the term “cost function” *per se* is not limited to the formulas and variables of column 13. Claim 25 does not have any dependent claims that similarly recite how the cost function is obtained, or otherwise recite those formulas or variables. However, dependent claim 2 further recites how the “cost function” of claim 1 is obtained. Those limitations include the formulas and variables set out in column 13, lines 4-19 (paragraphing added), with some differences:

2. The method of claim 1 wherein the cost function is obtained by the steps of:

determining a CDVH associated with the desired dose prescription;

assigning zones to each CDVH;

assigning weights to each zone, applicable to the CDVHs associated with both the desired dose prescription and the proposed radiation beam arrangement;

calculating a zone cost for each target and each structure, according to the following formula:

$$C_z = W_z * (A_p / A_d),$$

Col. 13, lines 4-39:

“In the cost function of the present invention,

each region, or zone, of the CDVH

is assigned a relative weight, according to the importance of that region, or zone, of the CDVH.

A zone cost is then calculated for the target and each structure, according to the following formula:

$$C_z = W_z * (A_p / A_d),$$

where C_z is the cost for the current zone, W_z is the weight assigned to the current zone, A_p is the area or length of the current zone of the proposed CDVH, and where A_d is the area or length of the current zone of the desired CDVH;

calculating a target or structure cost for each target or structure, according to the following formula:

$$C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}, \text{ and}$$

$$C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$$

where C_S and C_T are the cost for each structure or zone, and C_{z1} , C_{z2} , C_{z3} , and C_{zn} are the costs calculated for each zone of the first, second, and third, through nth zone of each target or structure; and

calculating a total cost for the change in the proposed radiation beam arrangement, according to the following formula:

$$C_{Total} = C_S + C_T,$$

where C_{Total} is the total cost of the proposed change to the radiation beam arrangement.

where C_z is the cost for the current zone, W_z is the weight assigned to the current zone, A_p is the area of the current zone of the proposed CDVH curve, or pseudo-curve, and where A_d is the area of the current zone of the desired CDVH curve except for target zone T7, where A_d is the length represented by target zone T7 and structure zone S8, where A_d is the length represented by structure zone S8.

After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula:

$$C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}, \text{ and}$$

$$C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$$

where C_S and C_T are the cost for each structure or zone, and C_{z1} , C_{z2} , C_{z3} , and C_{zn} are the costs calculated for each zone of the first, second, and third, through nth zone of each target or structure.

The total cost for the change to the proposed beam distribution is then calculated, according to the following formula:

$$C_{Total} = C_S + C_T,$$

where C_{Total} is the total cost of the proposed change to the beam distribution.”

Claim 35 depends from a claim (33) that does not use the term “cost function.” However, claim 35 indicates that “cost function parameters” may vary. Claim 44 likewise depends from a claim (40) that does not use the term “cost function.” Claim 44 uses the term “cost function” in much the same way as does claim 25, namely, without the formulas and variables urged by Accuray:

33. A method of determining an optimized radiation beam arrangement for applying radiation to at least one tumor target volume while minimizing radiation to at least one structure volume in a patient, comprising the steps of:

distinguishing each of the at least one tumor target volume and each of the at least one structure volume by target or structure type, wherein the target or structure types are distinguished as either Biologically Uniform or Biologically Polymorphic;

determining desired partial volume data for each of the at least one target volume and structure volume associated with a desired dose prescription;

entering the desired partial volume data into a computer;

in response to the desired partial volume data and in response to the target or structure type of each of the at least one tumor target volume and each of the at least one structure volume,

using the computer to computationally calculate an optimized radiation beam arrangement.

35. The method of claim 33, wherein the optimized radiation beam arrangement is calculated using different cost function parameters depending on the target or structure type.

40. A method of determining an optimized radiation beam arrangement for applying radiation to at least one tumor target volume while minimizing radiation of at least one structure volume in a patient, comprising the steps of:

determining desired partial volume data for each of the at least one target volume and structure volume associated with a desired dose prescription;

entering the desired partial volume data into a computer;

in response to the desired partial volume data, using the computer to computationally approximate desired CDVHs for each of the at least one target and structure associated with the desired dose prescription; and

using the computer to computationally calculate the optimized radiation beam arrangement associated with the CDVHs approximated by the computer.

44. The method of claim 40, wherein the CDVHs approximated by the computer are approximated by the steps of:

using the computer to computationally obtain a set of proposed beam weights;

using the computer to computationally change the set of proposed beam weights iteratively, incorporating a cost function at each iteration to determine a cost of the change to the set of proposed beam weights; and

rejecting the change to the set of proposed beam weights if the change to the set of proposed beam weights leads to a lesser correspondence to the desired CDVHs and accepting the change to the set of proposed beam weights if the change to the set of proposed beam weights leads to a greater correspondence to the desired CDVHs.

Similarly, claims 14 and 18 recite much of what the cost function of column 13 includes, but without the formulas and variables:

14. A method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising the steps of:

(a) determining a desired CDVH associated with each target and structure;

(b) using a computer to iteratively compare a cost of a radiation beam arrangement proposed during a given iteration to a radiation beam arrangement proposed during the previous iteration based on the relative costs associated with the proposed radiation

18. A method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising the steps of:

determining a desired CDVH for each of at least one target or structure, representing the desired cumulative effect of a radiation dose to be applied to the patient;

calculating a proposed radiation beam arrangement proposed to be applied to the patient, associated with a total dosage cost;

Col. 13, lines 4-39:

“In the cost function of the present invention,

beam arrangement, the costs being calculated by:

(1) determining a CDVH associated with each target and structure based on the proposed radiation beam arrangement of a given iteration;

(2) assigning cost zones to the desired CDVH and the proposed CDVH of a given iteration associated with each target and structure;

(3) assigning a weight value to each cost zone of each CDVH associated with each target and structure;

(4) for each target and structure, multiplying the weight value of each zone by the quotient of a value representing the area of the zone of the CDVH associated with the proposed radiation beam arrangement and a value representing the area of the zone of the CDVH associated with the desired radiation beam arrangement;

creating a proposed CDVH for each of the at least one target or structure, representing the cumulative effect of the proposed radiation beam arrangement;

assigning a plurality of cost zones for each of the desired CDVHs;

assigning a zone weight for each of the plurality of cost zones of each of the CDVHs;

determining a zone cost value representing a zone cost for each cost zone of each CDVH of each target and structure for each of the plurality of cost zones of each of the desired CDVHs by multiplying a value representing the cost zone's zone weight by a value representing the quotient of a value representing the cost zone's zone area bounded by the proposed CDVH and a value representing the cost zone's zone area bounded by the desired CDVH;

each region, or zone, of the CDVH

is assigned a relative weight, according to the importance of that region, or zone, of the CDVH.

A zone cost is then calculated for the target and each structure, according to the following formula:

$$C_z = W_z * (A_p / A_d),$$

where C_z is the cost for the current zone, W_z is the weight assigned to the current zone, A_p is the area of the current zone of the proposed CDVH curve, or pseudo-curve, and where A_d is the area of the current zone of the desired CDVH curve except for target zone T7, where A_d is the length represented by target zone T7 and structure zone S8, where A_d is the length represented by

(5) summing the results of step (4) for each zone of each CDVH of each target and structure to obtain a total dosage cost;

determining a total target cost value representing a cost of the proposed radiation beam arrangement for each of the at least one target by summing the zone cost values of each of the at least one target;

determining a total structure cost value representing a cost of the proposed radiation beam arrangement for each of the at least one structure by summing the zone cost values of each of the at least one structure; and

determining a total dosage cost value representing the total cost of the proposed radiation beam arrangement by summing each target cost value and each structure cost value.

(c) accepting the proposed radiation beam arrangement of a given iteration if the total dosage cost of a given iteration is less than the total dosage cost of the previous iteration;

structure zone S8.

After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula:

$$C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$$

and

$$C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$$

where C_S and C_T are the cost for each structure or zone, and C_{z1} , C_{z2} , C_{z3} , and C_{zn} are the costs calculated for each zone of the first, second, and third, through nth zone of each target or structure.

The total cost for the change to the proposed beam distribution is then calculated, according to the following formula:

$$C_{Total} = C_S + C_T,$$

where C_{Total} is the total cost of the proposed change to the beam distribution.”

<p>(d) rejecting the proposed radiation beam arrangement of a given iteration if the total dosage cost of a given iteration is greater than the total dosage cost of the previous iteration; and</p> <p>(e) repeating steps b-d until the proposed radiation beam arrangement has a total dosage cost value within an acceptable level to obtain an optimized radiation beam arrangement.</p>		
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Again, differentiation among claims may have evolved from what Chief Judge Markey characterized as having “immutable and universally applicable status comparatively rare among rules of law,” to a “guideline;” nevertheless, asserted and non-asserted claims remain an objective source, outside the scope of litigation-induced proposed constructions, for evaluating the scope of the term “cost function.” Other asserted and non-asserted claims indicate that the “cost function” of claim 1 is not limited to the equations recited in claim 2. Particularly in view of the largely parallel elements of claims 1 and 25, the above comparison indicates that the “cost function” recited in claim 25, like the “cost function” of claim 1, should not be limited to the formulas shown in column 13, lines 4-39. *See Curtiss-Wright Flow Control*, 438 F.3d at 1380 (“Beyond the independent/dependent claim scenario, this court has characterized claim differentiation more generally, *i.e.*, as the ‘presumption that each claim in a patent has a different scope.’ ” (*quoting Versa Corp. v. Ag-Bag Int’l Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004))); *Phillips*, 415 F.3d at 1314 (“Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.”). Similarly, claim 25 should not be limited to the cost function calculations of claim 14, for example. Indeed, as claim 35 indicates, a “cost function” may have a variety of “different cost function parameters.”

(2) Specification

(a) Ordinary and Customary Meaning

The patentees used the term “cost function” in describing prior art techniques, indicating that the term “cost function” had an accepted meaning in the art at the time of filing. According to the patentees in the section of the specification entitled “Background of the Invention,” “[e]xisting methods and apparatus utilize a computational method of establishing optimized treatment plans based on an objective cost function that attributes costs of radiation of various portions of both the tumor and surrounding tissues, or structures.” Col. 3, lines 17-21 (emphasis added). The patentees explain that “[o]ne such computational method is known in the art as simulated annealing. Existing simulated annealing methods utilize cost functions that consider the costs of under-exposure of tumor volumes relative to over-exposure of surrounding structures.” Col. 3, lines 21-25 (emphasis added). However, “the cost functions used in existing methods” apparently:

- “do not account for the structure volumes as a whole, relying merely on costs related to discrete points within the structure,”
- “do not account for the relative importance of varying surrounding structure types,” and
- “do not allow the physician to utilize the familiar partial volume data associated with Cumulative Dose Volume Histogram (“CDVH”) curves in establishing the desired dose distributions.”

Col. 3, lines 25-52.

It is further clear from the patentees’ disclosure of the claimed invention that they did not provide a special definition for “cost function,” or disavow the ordinary scope of that term. *See Interdigital*, slip op. at 10 (“Claim terms are generally given their ordinary meaning as understood by persons skilled in the art in question at the time of the invention. * * * The plain meaning of claim language ordinarily controls unless the patentee acts as his own lexicographer and provides a special definition for a particular claim term or the patentee disavows the ordinary scope of a claim term either in the specification or during prosecution.”). In the section of the specification entitled “Detailed Description of the Invention,” at column 13, the patentees describe a cost function in considerable detail:

In the cost function of the present invention, each region, or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone,

of the CDVH. A zone cost is then calculated for the target and each structure, according to the following formula:

$$C_z = W_z * (A_p / A_d),$$

where C_z is the cost for the current zone, W_z is the weight assigned to the current zone, A_p is the area of the current zone of the proposed CDVH curve, or pseudo-curve, and where A_d is the area of the current zone of the desired CDVH curve except for target zone T7, where A_d is the length represented by target zone T7 and structure zone S8, where A_d is the length represented by structure zone S8. After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula:

$$C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}, \text{ and}$$

$$C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$$

where C_S and C_T are the cost for each structure or zone, and C_{z1} , C_{z2} , C_{z3} , and C_{zn} are the costs calculated for each zone of the first, second, and third, through n th zone of each target or structure. The total cost for the change to the proposed beam distribution is then calculated, according to the following formula:

$$C_{\text{Total}} = C_S + C_T,$$

where C_{Total} is the total cost of the proposed change to the beam distribution.

Col. 13, lines 4-39. However, as Best Medical notes, immediately preceding that section is the following sentence:

The cost function is an analytical determination of whether, when any change is made to the strengths of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user.

Col. 13, lines 1-4. *See also* col. 9, lines 34-40 (“The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose.” (emphasis added)). That sentence describes “cost function” in a manner consistent with the patentees’ use of that term to describe prior art cost functions, *i.e.*, that prior art cost functions “attribute[d] costs of radiation of various portions of both the tumor and surrounding tissues, or structures,” and “consider[ed] the costs of under-exposure of tumor volumes relative to over-exposure of surrounding structures.” That general description of “cost function” is also consistent with Accuray’s technical description of prior art cost functions, also described above.

**(b) The Specification's Use of "present invention"
Language**

It is true, as Accuray notes, that the cost function of column 13 is the only cost function disclosed in detail in the '283 patent. However, for the same reasons discussed in connection with SARP, that fact does not, by itself, require limiting the "cost function" of claim 25 to the formulas and variables described in column 13. The Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Phillips*, 415 F.3d at 1323.

Accuray nevertheless urges that the patentees' use of the phrase "the present invention" in connection with the cost function described in column 13, lines 4-39, essentially defines the scope of the term "cost function." See, e.g., *Markman* Tr. at 141. As might be expected in view of the disagreement regarding the role of the specification in claim construction, Federal Circuit judges vary in how much weight they give such language. For example, Judge Lourie relied on such language in limiting claim scope in *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322 (Fed. Cir. 2009) (Circuit Judges Lourie, Rader and Moore). According to the opinion in *Edwards Lifesciences*, the technology in that case related to "intraluminal grafts for treating aneurisms and occlusive diseases of the blood vessels without open surgery." *Id.* at 1324. The district court had agreed with Cook in construing the claim term "graft" to be "intraluminal" "because the specification used the term 'graft' as shorthand for 'intraluminal graft' and referred to an 'intraluminal graft' as 'the invention,' " and because "the claimed 'graft' could not encompass a traditional surgically implanted vascular graft because all of the disclosed embodiments contained wires, which the parties agreed are a feature of intraluminal grafts." *Id.* at 1326. Edwards urged on appeal that "graft" should not be so limited because (1) modification of the word "graft" with "intraluminal" in the specification indicated that not all grafts were necessarily intraluminal, (2) some, but not all of the claims included an "intraluminal" limitation," (3) the modifier "intraluminal" was deleted from some claims during prosecution, and (4) declarations during prosecution provided evidence that the inventors intended a broader meaning. *Id.* at 1328-29. The Federal Circuit, however, agreed with the district court.

Judge Lourie, in writing for the panel, concluded that "in light of the specification's written description, the claimed 'graft' devices must all be intraluminal." Judge Lourie reasoned that (1) "the specification consistently uses the words 'graft' and 'intraluminal graft' interchangeably," and that "[t]he interchangeable use of the two terms is akin to a definition equating the two;" (2) "the only

devices described in the specification are intraluminal, supporting an interpretation that is consistent with that description;” (3) “the specification frequently describes an ‘intraluminal graft’ as ‘the present invention’ or ‘this invention,’ indicating an intent to limit the invention to intraluminal devices;” (4) “the claim language itself,” in that the claims without the “intraluminal” modifier separately “require that the two graft bodies be attachable ‘while inside of a vessel,’” and “‘intraluminal’ specifically means ‘inside of a vessel;’” (5) “claim differentiation does not require that ‘graft’ be read differently from ‘intraluminal graft,’” in part because construing them identically did not lead to redundancy; (6) during prosecution, the amendment removing the “intraluminal” modifier included “accompanying remarks stat[ing] that ‘[i]ndependent claim 12 defines an intraluminal graft;’” (7) the declarations to “were submitted only for the purpose of provoking an interference,” and “the Patent Office never issued a notice of interference in this case, and thus we cannot infer that the examiner relied on the declarations for any reason.” *Id.* at 1328-31. Although, as noted above, Judges Moore and Rader later disagreed with Judge Lourie in the *Retractable* case and denial of rehearing over the role of the specification in claim construction, they did not express dissent here.

However, Judge Rader, in writing for the panel in *Absolute Software Inc. v. Stealth Signal Inc.*, did not view such language as necessarily limiting. Judge Rader noted that “present invention” language can limit claim scope in some circumstances:

It is true that, in some circumstances, a patentee’s consistent reference to a certain limitation or a preferred embodiment as ‘this invention’ or the ‘present invention’ can serve to limit the scope of the entire invention, particularly where no other intrinsic evidence suggests otherwise. *See Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007) (‘When a patent thus describes the features of the ‘present invention’ as a whole, this description limits the scope of the invention’); *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006) (noting that, ‘[o]n at least four occasions, the written description refers to [only one particular component] as ‘this invention’ or the ‘present invention’ and finding that the prosecution history does not support a broader scope).

659 F.3d 1121, 1136 (Fed. Cir. 2011) (Chief Judge Rader and Circuit Judges Prost and O’Malley). Judge Rader wrote that whether “present invention” language is limiting depends on how that language is used:

On the other hand, we have found that use of the phrase ‘present invention’ or ‘this invention’ is not always so limiting, such as where the references to a certain limitation as being the ‘invention’ are not uniform, or where other portions of the intrinsic

evidence do not support applying the limitation to the entire patent. *See Voda v. Cordis Corp.*, 536 F.3d 1311, 1320–22 (Fed. Cir. 2008) (although parts of the specification referred to a certain embodiment as the ‘present invention,’ the specification did not uniformly refer to the invention as being so limited, and the prosecution history did not reveal such a limitation); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1326 (Fed. Cir. 2008) (references to a specific embodiment as ‘the apparatus of this invention’ and ‘a useful feature of this invention’ in the specification ‘are contradicted by a number of express statements in the ‘609 specification clearly indicating that [the feature at issue] is a feature only of certain embodiments’); *Rambus, Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1094–95 (Fed. Cir. 2003) (although portions of the written description referred to the term at issue as limiting the claimed invention to a preferred embodiment, ‘the remainder of the specification and the prosecution history shows that Rambus did not clearly disclaim or disavow such claim scope in this case’).

Id. at 1136-37.

According to the opinion in *Absolute Software*, the technology at issue related to “retrieving lost or stolen electronic devices such as laptop computers, personal digital assistants (PDAs), and cell phones, via a global network, such as the Internet.” *Id.* at 1125. The district court had construed the term “semi-random rate” as “normally taking place exactly once at a randomly chosen time during each occurrence of a repeating predetermined time interval.” *Id.* at 1135. The parties “disputed the degree of randomness required for the message transmission, specifically whether the claim is limited to a random call within a ‘predetermined time interval,’ such as once per day, week, or month, as Absolute urged, or whether no such time interval limitation exists, which Stealth argued.” *Id.* The district court had “placed significant weight on the fact that the specification refers to an embodiment designed to make one call during a specified time period as the ‘present invention:’ ”

Specifically, the relevant text of the ‘269 Patent describes the randomizer of Figure 2 as having two functions: (1) ensuring that there is “one call per time period, such as day/week/month”; and (2) making sure “that call is made randomly at only one time during that period.” That section states that “[t]he present invention is designed to make one, and only one, call during the selected period....” The specification also refers to Figure 1 as “a flow chart of the major functions performed by the present invention,” and states that Figure 2 is a detailed flow chart of the randomizer portion of Figure 1. The description of Figure 1, moreover, describes the preferred embodiment by saying that “[t]he monitoring system of the present invention is intended to be secretly included at the time of sale....”

Id. at 1135-36 (citations and emphasis omitted). The panel disagreed with the district court “that the references in the specification to the ‘present invention’ limit the entire invention to the preferred

embodiment.” The panel concluded that the patent at issue was “more like the patents at issue in *Voda*, *Praxair*, and *Rambus*, in that the specification does not uniformly refer to a one-call-per-time-period limitation as being co-extensive with the entire invention.” *Id.* at 1137. The panel noted that another portion of the specification “expressly describe[d] the features of a predetermined time interval and a random call during that interval as two optional features of the ‘present invention,’ ” and concluded that “[b]ecause the specification uses ‘present invention’ in a way that expressly contradicts earlier references to ‘present invention’ as requiring both one call during a time interval and the randomness of that call, we do not agree that the invention is so limited.” *Id.* The panel nevertheless concluded that “the asserted claims themselves, and the specification relating to those claims, otherwise support the district court’s construction that ‘semi-random rate’ includes a time interval limitation.” *Id.* at 1136.

Those – and other – cases may be compared or contrasted on their facts, but what is clear is that mere recitation of “the present invention” language is not dispositive. As with evaluating so-called “boilerplate” language, whether “the present invention” limits claim scope depends on how that phrase is used in the entirety of the intrinsic record. Here, in view of the entire intrinsic record, the “present invention” language that Accuray points to cannot be reasonably viewed as limiting “cost function” to the formulas and variables of column 13. It seems clear that the formulas and variables of column 13 were intended as part of the patentees’ required disclosure under § 112(1), including a disclosure of the applicants’ known best mode for practicing the invention, as opposed to a disclosure of the limits of the claimed invention.

(c) “Detailed Description of the Invention”

In the “Detailed Description of the Invention,” “present invention” language is used in connection with most of the disclosed subject matter, not just in connection with the disclosed “cost function.” For example, the specification uses that language in connection with the disclosed “optimizer:”

The optimizer of the present invention computes an optimized treatment plan, or beam arrangement, which should be understood to include either the optimal beam positions around the treatment field, the optimal array of beam weights, or beam intensities, otherwise known as an intensity map or a fluence profile or both.

Col. 9, lines 29-34 (emphasis added).

The specification also uses “present invention” language in connection with the disclosed “system:”

The system of the present invention includes an improved optimized treatment planning system, which accounts for multiple treatment parameters for both a target and multiple surrounding structure types.

Col. 9, lines 49-52 (emphasis added).

The specification further describes the “cost function” and “Prescription Panel step 802” as “of the present invention:”

[T]he familiar CDVH curves 100, 200 are used by a physician using the system of the present invention not only in the Output Process step 807 (FIG. 2), discussed hereinafter in detail, but also prior to the Plan Optimization step 803 (FIG. 2) to establish partial volume data representing dosage limits and other parameters, as hereinafter discussed in detail, for each target and structure to establish the input parameters for the cost function of the present invention, which may be entered in the Prescription Panel step 802 (FIG. 2) of the present invention.

Col. 10, lines 43-52 (emphasis added).

The specification similarly describes the “optimization method” as “of the present invention,” and refers to the “conformal radiation therapy of the present invention:”

The optimization method may be carried out using conventional equipment, including a conventional linear accelerator (“LINAC”) 300, as shown in FIG. 1, having a rotatable gantry, a conventional computer or set of computers, and plan optimization software, which utilizes the optimization method of the present invention.

FIG. 2 shows a procedure for creating a treatment plan utilizing the system of the present invention. The first step of the method is generally referred to as the Registration Process step 800. This is the process step of aligning a set of conventional axial slice images of the portion of the patient to be treated by the conformal radiation therapy of the present invention.

* * *

After the foregoing steps have been accomplished, the Delivery System step 808 is accomplished, wherein the method steps of the conformal radiation therapy method of the present invention are performed as previously described, in order to treat the tumor in the patient.

Col. 9, lines 59-64; col. 16, lines 21-25 (emphasis added).

Thus, in the “Detailed Description of the Invention,” the patentees described the “cost function of the present invention” in the context of the “optimizer of the present invention,” the “system of the present invention,” the “Prescription Panel step 802 (Fig. 2) of the present invention,” the “optimization method of the present invention,” and the “conformal radiation therapy of the present invention” and the “conformal radiation therapy method of the present invention.” That is, the patentees described most of the subject matter in the “Detailed Description” as “of the present invention,” and do not single out the “cost function” as being particularly “of the present invention.” That is also clear from section of the specification entitled “Brief Description of the Drawings:”

In the drawings:

FIG. 1 is a perspective view of a conventional linear accelerator, including a rotatable couch, collimator and gantry;

FIG. 2 is a flow diagram of a radiation planning system for controlling the operation of the apparatus of the present invention;

FIG. 3 is a target CDVH curve used in the system of the present invention;

FIG. 4 is a structure CDVH curve used in the system of the present invention;

FIG. 5 is a prescription panel of the system of the present invention;

FIG. 6A is a dose treatment, showing the dose relationship of a single treatment beam passing through a treatment field; and

FIG. 6B is a dose treatment, showing the dose relationship of two beams passing through a treatment field.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as to be defined by claims to be filed in a non-provisional application.

Col. 8, lines 31-57 (emphasis added).

Furthermore, in the “Detailed Description of the Invention,” the patentees do not uniformly describe the “cost function of the present invention” only in the context of the formulas and variables of column 13, or in a way that refers to those formulas or variables. Again, in connection with the disclosed “optimizer:”

The optimizer of the present invention computes an optimized treatment plan, or beam arrangement, which should be understood to include either the optimal

beam positions around the treatment field, the optimal array of beam weights, or beam intensities, otherwise known as an intensity map or a fluence profile or both. The optimal beam arrangement is arrived at by computationally increasing the proposed beam weight iteratively, incorporating cost functions to ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose. At each iteration, the dose distribution resulting from the proposed beam selection is compared to a prescribed dose for the tumor volume and surrounding tissue structures. If the increase or decrease in beam weights would lead to a greater correspondence to the desired prescription, the change is accepted. Ultimately, the SARP method will produce an optimized treatment plan, based on the treatment objectives as expressed by the cost function incorporated in the SARP algorithm.

Col. 9, lines 29-48 (emphasis added). The “optimizer” is said to “incorporate cost functions,” but does not describe those “cost functions” requiring any particular algorithm. Rather, the reference to “cost functions” (plural) indicates that more than one cost function may be suitable for use with the “optimizer of the present invention.” Indeed, the description of what the optimizer’s “cost function” does, namely, “ensure that an iterative change in the beam weight would not result in an unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed dose,” is consistent with the ordinary and customary meaning of the term.

Similarly, the patentees describe the “system of the present invention” as using a “modified cost function:”

The system of the present invention includes an improved optimized treatment planning system, which accounts for multiple treatment parameters for both a target and multiple surrounding structure types. The system includes a modified cost function, which allows a physician to use conventional cumulative dose volume histograms (‘CDVH’s) to establish a desired prescription of dosage to both the target volume, or target, and each involved structure volume, or structure, which will then be used as input for the system for determining the proposed radiation dose distribution for delivery to a patient.

Col. 9, lines 49-59 (emphasis added). In using the word “modified,” the patentees indicate a more particular “cost function,” namely, one that “allows a physician to use conventional cumulative dose volume histograms (‘CDVH’s) to establish a desired prescription of dosage to both the target volume, or target, and each involved structure volume, or structure, which will then be used as input for the system for determining the proposed radiation dose distribution for delivery to a patient.” The specification does not, however, here describe the “modified cost function” of the “system of

the present invention” as requiring any particular algorithms, only that it uses CDVH to establish a desired radiation dose prescription.

The specification reiterates that in a number of places, emphasizing use of CDVH curves in the optimization planning process as a point of distinction over prior practices:

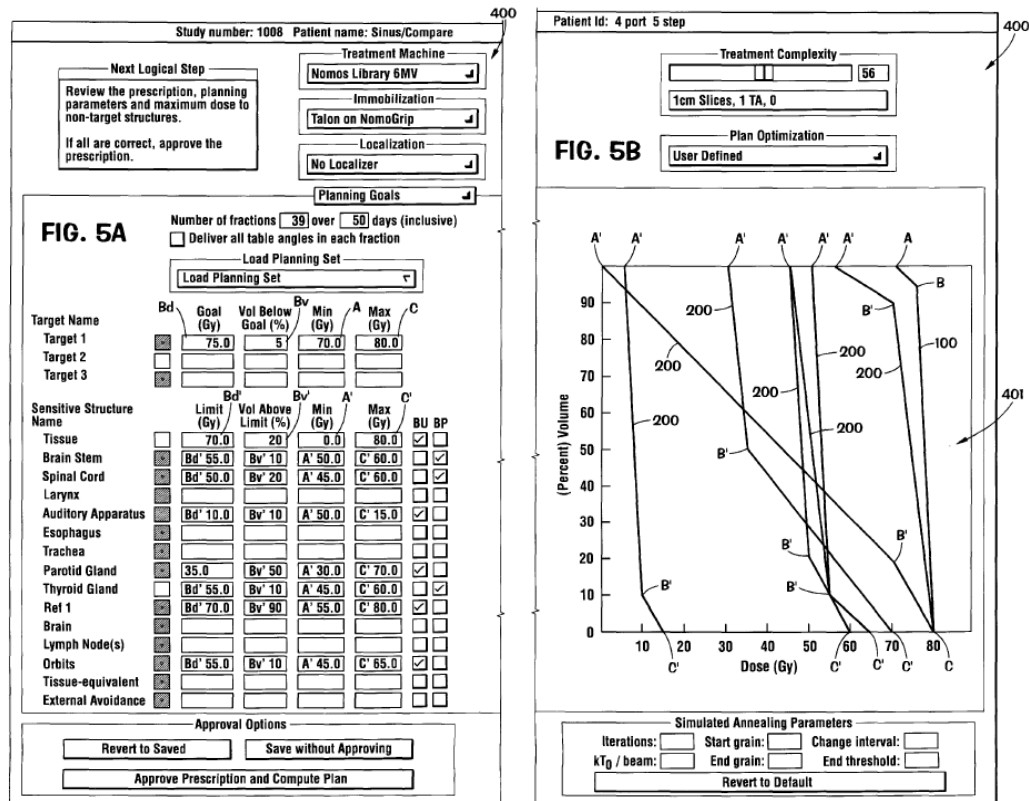
Physicians and those skilled in the art of radiation dosimetry are familiar with CDVH curves 100, 200; however, they are typically used to analyze a dose distribution after a treatment plan has been optimized. In contrast, the familiar CDVH curves 100, 200 are used by a physician using the system of the present invention not only in the Output Process step 807 (FIG. 2), discussed hereinafter in detail, but also prior to the Plan Optimization step 803 (FIG. 2) to establish partial volume data representing dosage limits and other parameters, as hereinafter discussed in detail, for each target and structure to establish the input parameters for the cost function of the present invention, which may be entered in the Prescription Panel step 802 (FIG. 2) of the present invention.

Col. 10, lines 39-52 (emphasis added). Here, the specification emphasizes use of CDVH curves as part of the planning process (i.e., at step 802), not particular formulae or variables. The specification explains that further:

The CDVH curves 100, 200 utilized in the system of the present invention are created from partial volume data for each target and structure of a given patient. In the system of the present invention, partial volume data are entered by the user during the Prescription Panel step 802 (FIG. 2). FIG. 5 shows an embodiment of a prescription panel 400 used to input the partial volume data into the planning system of the present invention. The partial volume data generally describes what percent of the volume of a tumor or structure can receive how much dose.

Col. 10, lines 53-62 (emphasis added).

In other words, the CDVH curves are based on partial volume data. That partial volume data may be provided numerically (as in Fig. 5A on the left, below), and CDVH curves may be generated from that data (as in Fig. 5B on the right, below):



See col. 12, lines 21-26 (“FIG. 5 shows an embodiment of a prescription panel 400 used in the Prescription Panel step 802 of the present invention in which numerical values are entered for the partial volume data for each target and structure. The corresponding target and structure CDVH curves 100, 200 are displayed in a graphical window 401.” (emphasis added)).

The specification explains that for both target and structure, a physician may input partial volume data numerically, or may graphically manipulate the CDVH curves to generate goal values:

“After the physician has input the **desired target goals** into the system according to the Prescription Panel step 802 (FIG. 2), the system of the present invention may display the corresponding target CDVH curve 100 for review by the physician. Alternatively, the physician may be able to draw the target and structure CDVH curves 100, 200 graphically

“After the physician has input the **desired structure goals** into the system according to the Prescription Panel step 802 (FIG. 2), the system of the present invention may display the corresponding target and structure CDVH curves 100, 200 for review by the physician. Alternatively, the physician may be able to draw the target and structure CDVH curves 100, 200

using a mouse or other pointing device and the system would then present the numeric values representing the target goals corresponding to the CDVH curves 100, 200.”

Col. 11, lines 27-35 (emphasis added).

graphically using a mouse or other pointing device and the system would then present the numeric values representing the target goals corresponding to the CDVH curves 100, 200.”

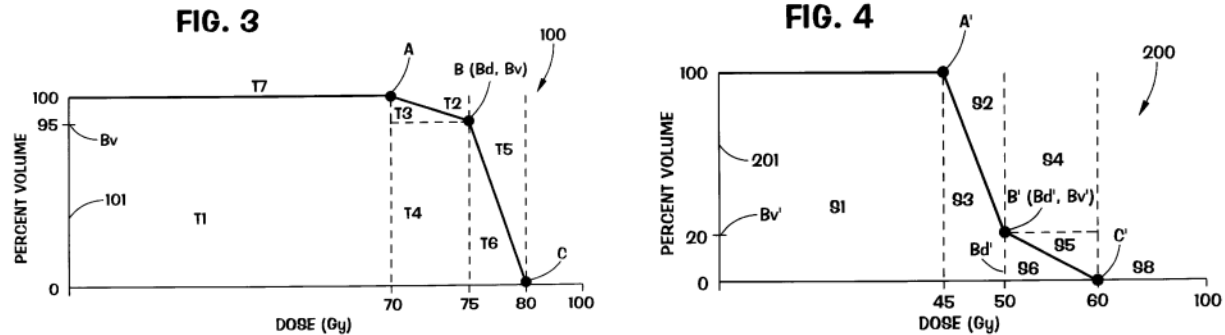
Col. 12, lines 4-13 (emphasis added).

After describing the foregoing, the specification states:

In the Plan Optimization step 803, the radiation plan optimization is a specific case of an inverse problem, where the goal is to determine the best way to achieve the dose prescription. A SARP technique is utilized to do this optimization by dividing the radiation delivery into a large number of small beams, each of which hit the target. The annealing cooling schedule utilized, fits into the class of FSA (Fast Simulated Annealing) techniques. Except for the foregoing detailed description of the cost function utilized in the present system, the details of the foregoing simulated annealing techniques are known in the art and are described in such publications as “Optimization of Conformal Radiotherapy Dose Distributions by Simulated Annealing”, S. Webb, Physics and Medical Biology, Vol. 34, PP. 1349-1370 (1989); and “Optimization of Conformal Radiotherapy Dose Distributions by Simulated Annealing: 2. Inclusion of Scatter in the 2d Technique”, S. Webb, Physics and Medical Biology, vol. 36, pp. 1227-1237, (1991), which publications are incorporated herein by reference. A suitable computer is utilized in performing the Plan Optimization step, as well as the other steps of the radiation planning system.

Col. 12, lines 27-47 (emphasis added). The “foregoing detailed description of the cost function utilized in the present system” refers to the “modified cost function” discussed above. In other words, the optimization process was known, except for the foregoing “modified cost function, which allows a physician to use conventional cumulative dose volume histograms (‘CDVH’s) to establish a desired prescription of dosage to both the target volume, or target, and each involved structure volume, or structure, which will then be used as input for the system for determining the proposed radiation dose distribution for delivery to a patient.”

The specification immediately follows that statement with reference to the “preferred embodiment” CDVH curves 100 (target) and 200 (structure) of Figures 3 and 4, and discloses column 13’s formulas and variables of the “cost function of the present invention” in that context (Figs. 3 and 4 reproduced below for ease of reference):



Referring again to FIGS. 3 and 4, utilizing familiar target and volume CDVH curves such as target and volume CDVH curves 100, 200 (FIGS. 3 and 4), certain regions or zones of the CDVH curves may be identified as being more important for a particular type of target or structure. Relative weights are then assigned by the computer, after experimental generation by the user that will achieve the desired objective of each type of target or structure when applied by the cost function of the present invention, as further described below. In a preferred embodiment, target volume CDVH curve 100 (FIG. 3) comprises seven zones T1-T7. Zones T1-T6 represent areas above and below the target volume CDVH curve 100, while zone T7 represents the length of the line extending from the axis 101, representing the target volume, to the data point A, representing the target minus dosage value. Similarly, with reference now to FIG. 4, structure volume CDVH curve 200 (FIG. 4) may also comprise seven zones S1-S6, and S8. Zones S1-S6, and S8 each representing the respective areas above and below the structure CDVH curve 200.

Col. 12, lines 48-67 (emphasis added).

After discussing the various zones of the CDVH curves, the specification discusses the “cost function of the present invention, as further described below:”

The cost function is an analytical determination of whether, when any change is made to the strengths of the beams being used to treat the patient, the resultant dose distribution is closer to the result desired by the user. In the cost function of the present invention, each region, or zone, of the CDVH is assigned a relative weight, according to the importance of that region, or zone, of the CDVH. A zone cost is then calculated for the target and each structure, according to the following formula:

$$C_z = W_z * (A_p / A_d),$$

where C_z is the cost for the current zone, W_z is the weight assigned to the current zone, A_p is the area of the current zone of the proposed CDVH curve, or pseudo-curve, and where A_d is the area of the current zone of the desired CDVH curve except for target zone T7, where A_d is the length represented by target zone T7 and structure zone S8, where A_d is the length represented by structure zone S8. After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula:

$$C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}, \text{ and}$$

$$C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$$

where C_S and C_T are the cost for each structure or zone, and C_{z1} , C_{z2} , C_{z3} , and C_{zn} are the costs calculated for each zone of the first, second, and third, through n th zone of each target or structure. The total cost for the change to the proposed beam distribution is then calculated, according to the following formula:

$$C_{\text{Total}} = C_S + C_T,$$

where C_{Total} is the total cost of the proposed change to the beam distribution.

Col. 13, lines 1-39. The context in which the patentees disclose the formulas and variables of the “cost function of the present invention” is the “preferred embodiment” CDVH curves 100 and 200 of Figs. 3 and 4. The “zone cost formula” uses variable based on the particular zones of those CDVH curves. Variable A_d , for example, is couched in terms of the “target zone T7” and “structure zone S8.” Limiting the term “cost function” to the formulas and variables of column 13 would also effectively limit that term to the seven-zone CDVH curves of Figures 3 and 4.

That is not to say that those formulas and variables could not be perhaps used with other CDVH curves. As discussed further below, the patentees provide a broader recitation of those formulas and variables in the “Summary of the Invention.” The point here is that the patentees reiterated that the CDVH curves of Figures 3 and 4 were “a preferred embodiment,” and the formulas and variables as described in column 13 particularly pertain to that “preferred embodiment.” That is consistent with how the patentees described the subject matter disclosed in the “Detailed Description of the Invention” (including the cost function of column 13), namely, as the preferred embodiment. *See* Col. 8, lines 51-57. Indeed, despite the usage of the present invention, the patentees occasionally reiterate that the particular details disclosed in the “Detailed Description of the Invention” are “an embodiment” or “preferred embodiment.” For example, the “prescription panel 400” of Figure 5 (above) disclosed in connection with the “Prescription Panel

step 802 of the present invention” and “system of the present invention” is described as the “preferred embodiment:

FIG. 5 shows an embodiment of a prescription panel 400 used to input the partial volume data into the planning system of the present invention.

Col. 10, lines 7-60 (emphasis added). *See* col. 12, lines 13-20 (“In any event, the resulting CDVH curves for both the target and the structures can be compared to ensure that the structure curves fit within the bounds of the target curves. This can be accomplished by overlaying the graphs manually or, in a preferred embodiment, by simultaneously displaying the graphs alongside the numerical representations of the partial volume data, as shown in FIG. 5.” (emphasis added)); col. 12, lines 21-24 (“FIG. 5 shows an embodiment of a prescription panel 400 used in the Prescription Panel step 802 of the present invention in which numerical values are entered for the partial volume data for each target and structure.” (emphasis added)). *See also* col. 13, lines 60-63 (“For instance, in one implementation of the invention, sparing of sensitive structures is preferred over treating the entire target in order to avoid complications which can result from the delivery of radiation.” (emphasis added)).

Overall, the “Detailed Description of the Invention” does not clearly indicate that the patentees consistently referred to the disclosed “cost function” using “present invention” language. Rather, patentees used “present invention” language in a general sense with much of the subject matter disclosed in that section. Furthermore, use of “present invention” language in connection with the formulas and variables of column 13 is tempered by their disclosure in connection with what the patentees reiterated was “a preferred embodiment.” Indeed, the specification discloses the “cost function of the present invention” in broader terms, as is clear from description of the “modified cost function” said to be unknown at the time.

(d) “Summary of the Invention”

The patentees’ disclosure of “cost function” in the section of the specification entitled “Summary of the Invention” likewise indicates that “present invention” language should not limit the claimed “cost function” to the formulas and variables of column 13. In large part, the disclosure of this section of the specification parallels the claims. The patentees explain that “[i]n accordance with the invention, the foregoing advantages have been achieved through a method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while

minimizing radiation of a structure volume in a patient * * *.” Col. 4, lines 14-18 (emphasis added). The steps of that method are basically those set out in claim 1, and “incorporat[e] a cost function at each iteration to approach correspondence of a CDVH associated with the proposed radiation beam arrangement to a CDVH associated with a pre-determined desired dose prescription.” Col. 4, lines 21-24. The Summary then states that “[t]he cost function may be obtained” by a series of steps (compared with those of column 13):

<p>“determining a CDVH associated with the desired dose prescription;</p> <p>assigning zones to each CDVH;</p> <p>assigning weights to each zone, applicable to the CDVHs associated with both the desired dose prescription and the proposed radiation beam arrangement;</p> <p>calculating a zone cost for each target and each structure, according to the following formula:</p> $C_z = W_z * (A_p / A_d),$ <p>where C_z is the cost for the current zone, W_z is the weight assigned to the current zone, A_p is the area or length of the current zone of the proposed CDVH and where A_d is the area or length of the current zone of the CDVH;</p> <p>calculating a target or structure cost for each target or structure, according to the following formula:</p> $C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}, \text{ and}$ $C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$ <p>where C_S and C_T are the cost for each structure or zone, and C_{z1}, C_{z2}, C_{z3}, and C_{zn} are the costs</p>	<p><u>Column 13, lines 4-39</u></p> <p>“In the cost function of the present invention, each region, or zone, of the CDVH</p> <p>is assigned a relative weight, according to the importance of that region, or zone, of the CDVH.</p> <p>A zone cost is then calculated for the target and each structure, according to the following formula:</p> $C_z = W_z * (A_p / A_d),$ <p>where C_z is the cost for the current zone, W_z is the weight assigned to the current zone, A_p is the area of the current zone of the proposed CDVH curve, or pseudo-curve, and where A_d is the area of the current zone of the desired CDVH curve except for target zone T7, where A_d is the length represented by target zone T7 and structure zone S8, where A_d is the length represented by structure zone S8.</p> <p>After each zone cost is calculated, the target or structure cost is calculated for each target or structure, according to the following formula:</p> $C_T = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn}, \text{ and}$ $C_S = \sum C_{z1} + C_{z2} + C_{z3} + \dots C_{zn},$ <p>where C_S and C_T are the cost for each structure or zone, and C_{z1}, C_{z2}, C_{z3}, and C_{zn} are the costs</p>
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calculated for each zone of the first, second, and third, through n th zone of each target or structure; and

calculating a total cost for the change in the proposed radiation beam arrangement, according to the following formula:

$$C_{\text{Total}} = C_S + C_T,$$

where C_{Total} is the total cost of the proposed change to the beam arrangement.”

calculated for each zone of the first, second, and third, through n th zone of each target or structure.

The total cost for the change to the proposed beam distribution is then calculated, according to the following formula:

$$C_{\text{Total}} = C_S + C_T,$$

where C_{Total} is the total cost of the proposed change to the beam distribution.”

There are some differences between the two sections. For example, in the “Summary of the Invention,” the variable “ A_p is the area or length of the current zone of the proposed CDVH,” whereas in the “Detailed Description of the Invention,” “ A_p is the area of the current zone of the proposed CDVH curve.” The patentees thus describe a cost function that uses CDVH “in accordance with the invention,” but do not describe the subsequent formulas or variables in that way. Rather, by using the word “may,” the patentees indicate that the formulas and variables describe an optional way to implement the cost function. See *PSN Illinois, LLC*, 525 F.3d at 1164-66. That is consistent with the patentees’ description of those formulas and variables in connection with “a preferred embodiment.” That is also consistent with claim 1 and dependent claim 2, which sets out the formulas and variables of the “cost function” of claim 1.

The Summary also explains that “[i]n accordance with another aspect of the invention, the foregoing advantages have been achieved through a method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient * * *.” ‘283 patent, col. 5, lines 9-13. The steps of that method are basically those set out in claim 14, and “us[e] a computer to iteratively compare a cost of a radiation beam arrangement proposed during a given iteration to a beam arrangement proposed during the previous iteration based on the relative cost associated with the proposed radiation beam arrangements.” Those costs are said to be calculated by:

- (1) determining a CDVH associated with each target and structure based on the proposed radiation beam arrangement of a given iteration;
- (2) assigning cost zones to the desired CDVH and the proposed CDVH of a given iteration associated with each target and structure;

- (3) assigning a weight value to each cost zone of each CDVH associated with each target and structure;
- (4) for each target and structure, multiplying the weight value of each zone by the quotient of a value representing the area of the zone of the CDVH associated with the proposed radiation beam arrangement and a value representing the area of the zone of the CDVH associated with the desired radiation beam arrangement;
- (5) summing the results of step (4) for each zone of each CDVH of each target and structure to obtain a total dosage cost. [paragraphing added]

Col. 5, lines 20-34. According to the Summary, the cost calculations are used to determine whether to accept or reject the proposed radiation beam arrangement. *See* col. 5, lines 34-40. Those cost calculation steps largely state what column 13 describes, but without the formulas or variables. The patentees describe that as an “aspect” of the invention, not as “the present invention.” *See Warsaw Orthopedic, Inc. v. Globus Med. Inc.*, Case No. 2009-1525, slip op. at 4-5 (Fed. Cir. 2011) (**non precedential**) (“Globus argues that the claims are limited to the single embodiment disclosed in the common specification. We disagree. Although the ‘Description of the Illustrated Embodiments’ portion of the specification is devoted mainly to a detailed description of the preferred embodiment and some of its features, nothing in the specification indicates that the invention is limited to that embodiment. To the contrary, the ‘Summary of the Invention’ describes various ‘aspects’ of the invention in sufficiently general terms to embrace devices that embody the concept of the invention but are not identical to the particular embodiment that is described in great detail.”).

“In accordance with another aspect of the invention,” the Summary also states, “the foregoing advantages have been achieved through a method of determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient * * *.” Col. 5, lines 48-53 (emphasis added). The steps of that method are basically those set out in claim 18, and include, among other things, “determining a desired CDVH” for a target or structure, and “creating a proposed CDVH” for the target or structure. The Summary then describes how cost values are determined:

- assigning a plurality of cost zones for each of the desired CDVHs;
- assigning a zone weight for each of the plurality of cost zones of each of the CDVHs;
- determining a zone cost value representing a zone cost for each cost zone of each CDVH of each target and structure for each of the plurality of cost zones of each of the desired CDVHs by multiplying a value representing the cost

zone's zone weight by a value representing the quotient of a value representing the cost zone's zone area bounded by the proposed CDVH and a value representing the cost zone's zone area bounded by the desired CDVH;

determining a total target cost value representing a cost of the proposed radiation beam arrangement for each of the at least one target by summing the zone cost values of each of the at least one target;

determining a total structure cost value representing a cost of the proposed radiation beam arrangement for each of the at least one structure by summing the zone cost values of each of the at least one structure; and

determining a total dosage cost value representing the total cost of the proposed radiation beam arrangement by summing each target cost value and each structure cost value.

Col. 5, line 60-col. 6, line 14. Those steps largely correspond to what column 13 says, but again without mathematical notation. Here, as well, the patentees describe that as an "aspect" of the invention, not as "the present invention."

In short, the "Summary of the Invention" indicates that the patentees used the term "cost function" according to its ordinary and customary meaning, and their description of formulas and variables similar to those of column 13 as optional indicates that "cost function" should not be limited to the formulas or variables of column 13.

(e) "Background of the Invention"

According to the section of the specification entitled "Background of the Invention," the problems with the prior art were not that known cost functions failed to use the particular formulas and variables to characterize partial volume data associated with CDVH, but that the prior art cost functions did not allow physicians to use partial volume data associated with CDVH at all, nor did those cost functions fully account for various target volumes and target structures. As noted above, that section states:

Existing methods and apparatus utilize a computational method of establishing optimized treatment plans based on an objective cost function that attributes costs of radiation of various portions of both the tumor and surrounding tissues, or structures. One such computational method is known in the art as simulated annealing. Existing simulated annealing methods utilize cost functions that consider the costs of under-exposure of tumor volumes relative to over-exposure of surrounding structures. However, the cost functions used in existing methods do not account for the structure volumes as a whole, relying merely on costs related to discrete points within the structure, and further do not account for the relative importance of varying surrounding structure types. For example, certain

structure types are redundant in their function and substantial portions of the structure volume can be completely eradicated while retaining their function. Other structure types lose their function if any of the structure is completely eradicated. Therefore, the more sensitive structure volumes can receive a measured dose of radiation so long as no portion of the structure is subjected to a lethal dose.

Existing cost functions utilized in the optimization of treatment plans do not account for such varying costs associated with the different types of structures. After the treatment plan is optimized, the physician currently must evaluate each computed treatment plan for compliance with the desired treatment objective. If the computed treatment plan does not successfully meet the treatment objectives, the optimization process is repeated until a treatment plan can be computed that meets the physician's treatment objectives for both the tumor volume and the surrounding structures.

Further, existing methods and apparatus do not allow the physician to utilize the familiar partial volume data associated with Cumulative Dose Volume Histogram ("CDVH") curves in establishing the desired dose distributions.

Col. 3, lines 17-52 (emphasis added).

Thus, there was apparently a need for using CDVH or partial volume data in the planning process:

Therefore, the art has sought a method and apparatus for conformal radiation therapy, for use with a radiation beam having a predetermined, constant beam intensity for treatment of a tumor which:

- [1] is simple and economical to use;
- [2] that has what is believed to be a high safety factor for patient safety;
- [3] which computes an optimal treatment plan to meet conflicting, pre-determined, treatment objectives of a physician, accounting for objectives in both the target tumor volume and multiple structure types; and
- [4] which utilizes partial volume data or the associated CDVH curves in establishing the desired dose distributions for each target tumor volume and tissue and structure types.

Col. 3, line 66 to col. 4, line 10 (paragraphing, numbering and emphasis added).

The patentees indicated that their invention could do just that, *i.e.*, use CDVH curves or partial volume data in the planning process:

Accordingly, prior to the development of the present invention, there has been no method or apparatus for conformal radiation therapy, for use with a radiation

beam having a predetermined, constant beam intensity for treatment of a tumor which:

- [1] are simple and economical to use;
- [2] that has what is believed to be a high safety factor for patient safety;
- [3] which computes an optimal treatment ID plan to meet conflicting, pre-determined, treatment objectives of a physician, accounting for objectives in both the target tumor volume and multiple structure types; and
- [4] which utilizes partial volume data or the associated CDVH curves in establishing the desired dose distributions for each target tumor volume and tissue and structure types.

Col. 3, lines 53-65 (paragraphing, numbering and emphasis added).

That is, the patentees' disclosure of the claimed invention in the "Summary of the Invention" and the "Detailed Description of the Invention" is consistent with the problems that they said existed in the prior art, namely, that CDVH curves or partial volume data had not been used to establish desired radiation dose prescriptions before optimization, but were "typically used" after optimization. As the patentees later explained in the "Detailed Description of the Invention,"

Physicians and those skilled in the art of radiation dosimetry are familiar with CDVH curves 100, 200; however, they are typically used to analyze a dose distribution after a treatment plan has been optimized. In contrast, the familiar CDVH curves 100, 200 are used by a physician using the system of the present invention not only in the Output Process step 807 (FIG. 2), discussed hereinafter in detail, but also prior to the Plan Optimization step 803 (FIG. 2) to establish partial volume data representing dosage limits and other parameters, as hereinafter discussed in detail, for each target and structure to establish the input parameters for the cost function of the present invention, which may be entered in the Prescription Panel step 802 (FIG. 2) of the present invention.

Col. 10, lines 39-52. The CDVH curves and partial volume data were used "to establish the input parameters for the cost function of the present invention." In distinguishing prior art, the patentees focused on using CDVH curves or partial volume data for planning purposes to set dosage limits as input for a cost function, not on the particular formulas or variables of column 13. Accordingly, the patentees' description of the prior art and how the patentee distinguished the claimed invention further confirms that "cost function" should not be limited to the formulas or variables of column 13.

(f) Abstract

Similarly, the Abstract indicates that the cost function is not limited to the particular cost function disclosed at column 13 (emphasis added):

A method and apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, which uses an iterative cost function based on a comparison of desired partial volume data, which may be represented by cumulative dose volume histograms and proposed partial volume data, which may be represented by cumulative dose volume histograms for target tumors and tissue structures for delivery of the optimized radiation beam arrangement to the patient by a conformal radiation therapy apparatus.

The cost function is described as “iterative” and based on “a comparison of desired partial volume data” and “proposed partial volume data,” but not as necessarily including the formulas and variables described in column 13. *See Hill-Rom*, 209 F.3d at 1341 n.1 (“We have frequently looked to the abstract to determine the scope of the invention, and we are aware of no legal principle that would require us to disregard that potentially helpful source of intrinsic evidence as to the meaning of claims.” (citations omitted)).

(3) Prosecution History

The prosecution history of the ‘283 patent does not include a disavowal of claim scope concerning the term “cost function.” *Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008) (“[A]n applicant can make a binding disavowal of claim scope in the course of prosecuting the patent, through arguments made to distinguish prior art references. Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter.”). In the office action dated February 16, 1999, the examiner rejected certain claims under Leber stating that “Leber shows all of the features of the instant invention including radiation (therapy) beam optimization to a target volume and minimizing radiation to a structure volume, using a computer to modify the beam arrangement, and rejecting the new arrangement if it has a lesser correspondence to the desired radiation prescription (column 4 line 5 – column 6 line 2).” JCC, Exhibit 6, Office Action dated Feb. 16, 1999 at 2. While Leber does discuss a “cost function,” the applicant did not address the cost function in its response, but rather addressed the examiner’s rejection by adding the phrase “wherein the proposed radiation beam arrangement is changed by changing the beam weights.” *Id.* at Exhibit 6, Amendment at 2-4.

(4) Conclusion

The '283 patent uses the term "cost function" according to its ordinary and customary meaning. That use is consistent throughout the claims and specification, both in connection with description of the prior art and the claimed invention. The patentees' general and inconsistent use of "present invention" language throughout the specification does not require limiting "cost function" to the particular formulas and variables of column 13. Rather, the patentees described the "cost function" in much broader terms. Accuray's arguments to the contrary must therefore be rejected.

Accuray's arguments that failing to limit the "cost function" of claim 25 to the formulas and variables of column 13 would render claim 25 invalid over prior art, must also be rejected. Accuray's arguments that: (1) "the patentee concedes [*sic*] that everything in the patent is known in the art except the specific cost function," and (2) construing "cost function" according to its ordinary meaning "cannot possibly be correct because it would render the '283 patent is [*sic*] invalid over the Webb articles incorporated by reference and every other prior art reference that discloses treatment planning optimization," are simply two different ways of making that same argument. Again, whether invalidity would result is not a matter for resolution here in connection with claim construction. Accuray points to no ambiguity in claim 25 that would invite construing "cost function" as Accuray urges. See *Phillips*, 415 F.3d at 1327 ("While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction. Instead, we have limited the maxim to cases in which 'the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.' In such cases, we have looked to whether it is reasonable to infer that the PTO would not have issued an invalid patent, and that the ambiguity in the claim language should therefore be resolved in a manner that would preserve the patent's validity." (citations omitted)).

The Federal Circuit has emphasized that "[u]ltimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC*, 158 F.3d at 1250 (citations omitted). As noted above,

claim 25 is not the only claim that uses the term “cost function.” Claim terms “are normally used consistently throughout the patent,” *Phillips*, 415 F.3d at 1314, and construing “cost function” according to its ordinary and customary meaning provides the plainest reading of the claims (asserted claim 29 is couched in means-plus-function language and is construed accordingly, as discussed separately below). In view of the foregoing, the term “cost function” need not be defined as including the formulas and variables set out in column 13.

Nor does the foregoing discussion of the disclosure of “cost function” require express definition in terms of partial volume data, CDVH, target volume or structure type. Claim 25 expressly requires that the “computer” be “adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined derived dose prescription.”

c) Recommendation

In view of the foregoing, therefore, the master recommends that the Court conclude that the term “cost function” is not limited to the cost function of column 13, lines 4-39, of the ‘283 patent.

4. Whether “changing the beam weight” includes adding a beam or removing a beam

The third overarching dispute between the parties regarding claim 25 is whether the meaning of the term “changing the beam weights” includes changing the beam by adding or removing a beam. *See Markman* Tr. at 142.

Claim 25 calls for “changing the beam weight” as follows (emphasis added):

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration * * * *

a) The Parties' Proposed Constructions and Arguments

The parties' original proposed constructions are shown below:

<u>Term</u>	<u>BEST MEDICAL</u>	<u>ACCURAY</u>
"beam weights"	"the beam intensities or dose"	"beam intensities"
"changing the beam weights"	"changing (altering, varying or modifying) the beam weights (as construed above). The term 'change' does not require construction. To the extent that a construction is required, 'change' should be construed in accordance with its plain meaning: alter, vary or modify."	"adding or subtracting small quanta of positive and negative beam intensities to the beam elements randomly using the simulated annealing ('SARP') algorithm."

See JCC at 34-35.

Best Medical argues that its construction "conforms with what is understood by those skilled in the art." Best Medical's Brief at 14. Best Medical urges that Accuray stated that "beam weights and dose are synonymous" in a 2010 article entitled, "The CyberKnife® Robotic Radiosurgery System in 2010," which stated that "[t]he optimal set of relative weighting factors for the candidate beam set (*i.e.*, the dose delivered per beam) is obtained by inverse planning methods that are described later." *Id.*; Best Medical's Identification of Extrinsic Evidence, Exhibit 5 at 435.

Accuray responds that "[t]he specification discloses that the optimal beam arrangement is arrived at by changing the proposed array of beam weights at each iteration of the simulated annealing algorithm. Accuray's reply at 30. Accuray also argues that "[t]he specification further emphasizes that, except for 'the cost function utilized in the present invention,' *the details of the simulated annealing techniques are known in the art*, and are described in the Webb articles incorporated by reference. Thus, the only disclosure of how the simulated annealing algorithm works to change the proposed radiation beam arrangement iteratively is found in the Webb publications. Webb further explains that beam weights are beam intensities. "The [simulated annealing optimization] technique is iterative The method proceeds by *adding 'grains of beam intensity'* randomly to beam elements *Grains are small elements of beam intensity, randomly positive and negative.*" " *Id.* (citations omitted, Accuray's emphasis).

Accuray also argues that “[o]ne of skill in the art would have understood that the proposed array of beam weights is changed at each iteration of the simulated annealing algorithm by adding or subtracting random small amounts (grains) of beam weight. Unlike analytic methods, such as linear programming algorithms, simulated annealing is an iterative stochastic method that proposes a new beam weight solution at each iteration.” *Id.* at 30. According to Accuray, “[t]he Fast Simulated Annealing variant disclosed in the specification has shorter computational times, and adds occasional large grains, which allows escape from a local minimum without the need for accepting a conditionally worse solution.” *Id.* at 31. Accuray argues that “Dr. Carol’s contemporaneous publications confirm how one of skill in the art would understand the claim term ‘changing the proposed radiation beam arrangement iteratively.’ ”

The iterative approach to solving the optimization problem involves iteratively changing the strengths of the individual beamlets until a satisfactory solution is achieved.... Iterative systems typically require the user to assign graded weights and priorities to the structures and targets. By adjusting the relative weightings of the target and the surrounding structures, the planning systems will generate plans that vary greatly in the degree to which sensitive structures are spared and high dose lines conform to the three dimensional target contour. Ex. 2 at 57.

Peacock Plan starts with the desired dose distribution and works in reverse *to generate the beam weights* needed to produce this distribution. Peacock uses a *so-called fast simulated annealing process to determine a set of beam weights....The iterative planning process for changing beam weights* is driven by a cost function – the higher the cost associated with a particular change in beam weights, the less likely the system is to retain the change.

Iterative or stochastic methods ... are exemplified by simulated annealing, which as applied to radiation therapy treatment planning, *proceeds by randomly changing beam weights*, then evaluating the effect of each change on the dose distribution.... The *iterative changing of beam weights* continues until the cost reaches a user-designated acceptable level. Ex. 3 at 20[.]

Id. (Accuray’s emphasis).

Citing the Rosen Declaration, Accuray argues that “[o]ne of skill in the art would have understood that beam weights means ‘beam intensities,’ ” and that “[o]ne of skill in the art would have understood that beam weights, although related to dose, are not equivalent to dose.” *Id.* at 31. Accuray argues that “[b]y changing the beam weights at a particular iteration, a new proposed radiation beam arrangement would be generated. The change of beam weights at a particular iteration results in a new proposed radiation beam arrangement for that iteration, or a new proposed

solution for that iteration. Proposing a new solution at each iteration is consistent with how iterative, stochastic algorithms like simulated annealing work.” *Id.* at 31-32.

Accuray argues that “the only disclosure of ‘changing the proposed radiation beam arrangement iteratively’ is in the Webb articles.” *Id.* at 32. Accuray urges that “[t]he patentees **chose** to use Dr. Webb’s language in the specification (quoting him verbatim in portions of the specification). Further, the patentees **chose** to use claim language that mirrors Dr. Webb’s description of simulated annealing (*e.g.*, the claim terms ‘iteratively,’ ‘greater correspondence’). [Best Medical’s] attempt to disavow Webb’s teachings now to obtain a broader claim construction should be rejected.” *Id.* (citations omitted, Accuray’s emphasis).

Accuray argues that Best Medical’s “construction again reveals a lack of understanding of its technology. Beam weight refers to the beam intensity of a beamlet as it is emitted from the [multileaf collimator], whereas dose is the amount of radiation absorbed by the structure volume.” *Id.* According to Accuray, “[t]he optimized set of beam weights as delivered to the patient would result in a dose distribution, the beam weights of each beamlet that are changed during an iteration of simulated annealing do not correspond to a dose.” *Id.*

Best Medical replies that Accuray’s attempt to limit the scope of claim 25 by adding a negative limitation into the phrase “changing the beam weights” is improper. Concerning the amendment which added the phrase “wherein the proposed radiation beam arrangement is changed by changing the beam weights” to claim 25 during prosecution of the ‘283 patent, Best Medical argues that, “while Claim 25 was amended to affirmatively recite ‘changing the beam weights,’ the claim was determined amended [*sic*] to exclude ‘changing the beam geometry or position. Claim 25 was thus allowed because it added a feature, not because it excluded any ‘beam geometry or positions’ features.” Best Medical’s Reply at 25. At the *Markman* Hearing, Best Medical clarified its position by stating that “[b]eam weights were added to certain claims, they were not added to all claims. And there was no removal of beam geometry or orientation at the time that the beam weights were added.” *Markman* Tr. at 86. Best Medical stated that “[b]eam geometries was in and remained in the patent and in Claim 25 was not removed by adding of beam weights. I think – I guess a better way to describe this is in a beam arrangement you need beam geometry and/or beam weights is what the patent specification says. By the amendment, I believe what the patentee was

saying is you must have beam weights now that it has been added, but that doesn't exclude beam geometry or beam positions." *Id.* at 86-87.

Best Medical further contends that "[i]t is apparent that Accuray has added self-serving limitations. Because the phrase 'beam intensities' is included in Accuray's proposed construction, the addition of the terms 'adding and subtracting small quanta of positive or negative' and 'beam elements randomly at each iteration of the simulated annealing ('SARP') algorithm' are improper importations of extraneous limitations. The Court, when reviewing the disputed claim term can determine that there is nothing ambiguous about the term 'changing the beam weights.' Indeed, * * * Accuray's limitations are additions to the claim language, not constructions of any words in the disputed term." Best Medical's Reply at 25-26.

Best Medical also argues that "Accuray attempts to structure its construction by using improper justification for the addition of these extraneous limitations to the claim, but such additions change the claim language itself. The disputed terms clearly read: 'changing the beam weights,' but Accuray attempts to limit this term to only adding or subtracting an 'small quanta' of positive or negative beam intensities while using the simulated annealing algorithm (SARP) iteratively. However, the changing of beam intensities also allows for the removal of the entire beam or adding an entirely new beam, which Accuray simply ignores." *Id.* at 26. Best Medical also argues that Accuray's construction "limits the scope of the invention by not including changes smaller than the quanta and greater than the quanta, which may be used for faster and more efficient optimization." *Id.* Best Medical urges that "[t]he disputed claim term does not incorporate the language 'randomly at each iteration of the simulated annealing ('SARP') algorithm,' yet again another attempt by Accuray to support a case of non-infringement; thus, Accuray's construction is wrong." *Id.*

In reply, Accuray argues "[a]lthough [Best Medical] is technically correct that the Examiner allowed claims 1, 4 and 14 without amendment, that correction does not help its larger argument. The reason for allowance of claims 1, 4 and 14, which are method claims, was because they included CDVH limitations, which were not addressed by Leber." Accuray's Sur-Reply at 38. Accuray also argues that Best Medical "cites no case law for its argument that Accuray is attempting to improperly include a negative limitation that does not appear in the claim. [Best Medical] cites case law only for the irrelevant proposition that a claim using 'comprising' is 'open-ended.' The Examiner required

the applicant to amend the asserted claims to add the limitation ‘wherein the proposed radiation beam arrangement is changed by changing the beam weights,’ to overcome the anticipation rejection over Leber, and thus this limitation has patentable weight. Leber disclosed using ‘simulated annealing to optimize a plan based on criteria or predetermined parameters selected by the dose planner related to these involvement, coverage, beam arc, inhomogeneity or other specifications of the plan,’ and did not disclose optimization by changing beam weights.” *Id.* at 38-39.

Accuray argues that Best Medical “conceded that the specification supports a construction ‘radiation beam arrangement’ limited to an array of beam weights. *See* Doc. No. 134 at pp. 8, 10; Col. 9:29-34 (‘The optimizer of the present invention computes an optimized treatment plan or beam arrangement, which should be understood to include either the optimal beam positions around the treatment field, the optimal array of beam weights, or beam intensities, otherwise known as an intensity map or fluence profile or both.’). There is no disclosure of ‘optimal beam positions around the treatment field,’ and thus the proper construction must be ‘an array of beam weights.’” *Id.* at 38.

Accuray states that Best Medical “again argues that Accuray’s construction of ‘changing the beam weights’ improperly imports limitations by defining beam weights as ‘small quanta of positive or negative beam intensities.’ ” *Id.* at 39. Accuray urges that, “ ‘[a]dding and subtracting small quanta of positive or negative beam intensities’ comes straight from the Webb articles, which were incorporated by reference in the specification. Webb explains that simulated annealing works by adding or subtracting very small amounts (or quanta) of beam intensity randomly to each beamlet at each iteration, and running the algorithm through millions of iterations to obtain an optimized array of beam weights.” *Id.* (citations omitted).

Accuray argues that “[b]uried in its Reply Brief at page 26, [Best Medical] for the first time makes the ludicrous argument that ‘changing of beam intensities allows for the removal of the entire beam and adding an entirely new beam.’ Of course, [Best Medical] provides absolutely no intrinsic record support for this assertion, because there is none to be found. Nor does [Best Medical] argue that one of skill in the art would read the claims that way. Indeed, [Best Medical] cannot even point to a dictionary definition that would support this expansion from the claim term ‘changing the beam weights.’ ” *Id.* at 39-40. Accuray urges that Best Medical’s “proposed construction reads out the

term ‘weights’ from this limitation, in contravention of black letter patent law that states every word in a claim has meaning.” *Id.* at 40 (citations omitted).

Accuray also argues that “neither simulated annealing (nor any other optimization algorithm) optimizes beam weights **by adding or subtracting an entire beam**. The specification and the Webb articles incorporated by reference, disclose that each beam is divided into a large number of small beamlets, and the beam weight is changed for each beamlet individually. This disclosure is consistent with how one of ordinary skill in the art would have understood how simulated annealing works. Moreover, even if the entire weight was removed from a beamlet, the beamlet would still exist as part of beam, which has geometry (orientation and direction). Conceptually, adding or subtracting beam weight (beam intensity) is different from adding or subtracting an entire beam, which has both intensity and geometry.” *Id.* at 40 (emphasis added). Accuray argues that Best Medical “concedes, as it must, that beam position and beam intensity are two different aspects of radiation beams. Changing the beam weights cannot mean changing both beam position and beam intensity. [Best Medical’s] theory is speculative at best, as it has absolutely no intrinsic or extrinsic evidentiary support.” *Id.*

Accuray states that Best Medical “argues that Accuray’s ‘adding or subtracting small quanta’ limitation limits the scope of the invention by not allowing smaller or bigger changes for faster and more efficient optimization. [Best Medical] drastically expands the claim and attempts to untether it from the specification. Without a technical explanation, grounded in the intrinsic record, of how changing the beam weights can also change beam geometry, [Best Medical] construction is simply insupportable. Only by willfully ignoring the Webb articles, which provide the only detailed disclosure of how the only optimization algorithm, simulated annealing (SARP), works, can [Best Medical] make this argument.” *Id.* at 40-41.

At the *Markman* Hearing, Accuray argued that Best Medical would have “changing the beam weights” mean “that * * * you can remove a beam or you can add a beam and that’s changing the beam weight.” *Markman* Tr. at 143. Accuray urged that because Best Medical equated beam weight with dose, Best Medical meant that “changing the beam weights, going back to Figure 6A and 6B where you have first the one beam going through, then the second beam going through, that means you can remove a beam or you can add a beam and that’s changing the beam weight.” *Markman* Tr. at 143. Accuray further urged that “[t]here are some additional limitations which follow from the

way the simulated annealling [*sic*] algorithm works with respect to partial volume data, for example. I want to point out this disclosure in Webb which talks about how the simulated annealing algorithm works. It says: The aim is to grow the beam weight sonogram, or the collection of beam weights, the array of beam weights slowly, iteratively, in steps, and optimize the consistency between the dose distribution and the dose prescription. And how this works * * * is that the beam weights could be set to zero and then grains or very small amounts of beam weight are added at random to the beamlets.” *Id.* at 143-44.

At the *Markman* Hearing, Best Medical argued that “[t]he concepts of beam weights and dose are interrelated when you’re talking about 78 percent of the dose of the beam intensity. So this is where I believe the patent at least in addition to using beam weights and beam intensities adds in the concept of beam dose.” *Markman* Tr. at 85. Best Medical urged that beam weight and dose are “[d]ifferent but closely related.” *Id.* Best Medical also stated, citing Dr. Rosen, that “[b]eam weights determine the radiation doses in the patient, but are not doses. Physician’s treatment prescription is used to convert beam weights to dose.” *Id.* at 85-86. Best Medical urged:

Talking about Accuray’s construction of beam weights, Accuray argues that the applicant patents were required to amend the claims to add changing the beam weights in every claim, consistent with the understanding that optimized radiation beam arrangement is an array of beam weights and does not include beam geometry or orientation.

That is, in our opinion, incorrect. Beam weights were added to certain claims, they were not added to all claims. And there was no removal of beam geometry or orientation at the time that the beam weights were added. I would refer back to the slide mentioned earlier when we talked about beam arrangement, which should be understood to include either the optimal beam positions around the treatment field, optimal array of beam weights, or both. Beam geometries was in and remained in the patent and in Claim 25 was not removed by the adding of beam weights. I think – I guess a better way to describe this is in a beam arrangement you need beam geometry and/or beam weights is what the patent specification says. By the amendment, I believe what the patentee was saying is you must have beam weights now that it has been added, but that doesn’t exclude beam geometry or beam positions.

Id. at 86-87.

As noted above, Accuray urged that there were “three core disputes” between the parties in regards to claim construction, including the meaning of “changing the beam weights.” *Markman* Tr. at 141. With regard to beam weights, Accuray argued, “And then the third question is, what does

changing the beam weight mean? Does changing the beam weight mean changing the beam weight for the beam intensity, or does changing the beam weight also include changing the beam, like adding a beam or removing a beam?” *Id.* at 142. The master asked if Accuray understood that “Best Medical says [‘changing the beam weights’] includes changing the beam intensity?” *Id.* Accuray responded, “No, changing the beam.” *Id.* Accuray explained, “What they’ve said is beam weight equals beam intensity, they agree with us there, but then they say it also means dose. And, therefore, changing the beam weights, going back to Figure 6A and 6B where you have first the one beam going through, then the second beam going through, that means you can remove a beam or you can add a beam and that’s changing the beam weight. As Dr. Rosen explained about what beam weights are, they are intensities of those individual beamlets, and that dose is something very different. Dose is what you get when all of the radiation beams from the different orientations hit the tumor and are – or the tissue and are absorbed by the tissue and it’s measured there. Whereas the beam weight is up here, measured here with the individual beam weights.” *Id.* at 143.

b) Discussion

Based on Best Medical’s arguments at the *Markman* Hearing, it appears that Best Medical no longer argues that the term “beam weights” means “dose,” but simply that there is a “close correlation between beam weights and dose.” *Id.* at 86. Thus, the parties are in agreement that “beam weight” does not mean “dose.”

(1) Claim Language

As before, the analysis starts with the language of claim 25. Claim 25 calls for a computer adapted to change the “proposed radiation beam arrangement” by “changing the beam weights:”

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:

a computer, * * *

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights, * * *

The term “the beam weights” does not find antecedent basis in an earlier-recited “beam weights,” but there appears to be no dispute that “the beam weights” refers to beam weights of “the proposed radiation beam arrangement.” In other words, each “beam” of “the proposed radiation beam

arrangement” has a “weight,” and the weights of those beams is to be changed during each iteration. Claim 25 does not, on its face, exclude or require changing beam position, or adding or removing a beam. No other claim calls for that, either.

(2) Specification

According to the patentees, an optimized “beam arrangement” “should be understood to include either [1] the optimal beam positions around the treatment field, [2] the optimal array of beam weights, or beam intensities, otherwise known as an intensity map or a fluence profile or [3] both.” Col. 9, lines 29-34 (numbering added). That is, the patentees defined “beam arrangement” to include beam position or beam weight, or both. The patentees also make clear that “changing” the beam weights means increasing or decreasing the beam weights. Col. 9, lines 43-45 (“If the increase or decrease in beam weights would lead to a greater correspondence to the desired prescription, the change is accepted.”). In view of the specification’s clear distinction between beam position and beam weight, “changing the beam weights” does not mean changing beam position. The patentees also make clear that “beam intensities” and “beam weights” mean the same thing. *See also* col. 15, lines 48-52 (“The resulting optimized set of radiation beam positions and beam weights, or beam intensities for the radiation beam segments, is fitted into the delivery capabilities of the LINAC apparatus 300 (FIG. 1), after optimization.” (emphasis added)); col. 9, lines 16-20 (“The three-dimensional treatment field is shown projected on the two-dimensional grid 601. In this example, if a single beam is used, the beam weight, or intensity, at the epicenter 602 would be 78% of the dose at the entrance point 603.” (emphasis added)).

The patentees make that distinction further clear in “Instrument Fitting step 804,” in which the “resulting optimized set of radiation beam positions and beam weights is fitted into the delivery capabilities of the LINAC apparatus 300 (Fig. 1).” Col. 15, lines 49-52 (emphasis added). At some point before the Instrument Fitting step 804, therefore, both beam positions and beam weights are optimized. *See also* Fig. 2 (step 803: “Beam Position and Strength Optimization Performed”).

Thus, Best Medical is correct that patentees defined the claimed “beam arrangement” more broadly than just beam weights.

Accuray is correct, however, that the ‘283 patent does not appear to describe beam position optimization in the sense of changing beam positions in the same manner as changing beam weights. As discussed above, the patentees included optimizing radiation beam positions as part of

Optimization step 803. According to the patentees, the “resulting optimized set of radiation beam positions and beam weights” is used in the Instrument Fitting step (804).

The Strength Normalization step (805) is described as occurring after the Instrument Fitting step (804), so normalization cannot be the optimization of beam positions to which the patentees refer:

A Strength Normalize step 805 further normalizes the arcs of rotation through which the radiation beam source travels to insure that the tumor receives a consistent radiation dose from each position selected in order to eliminate what are known as ‘hot’ or ‘cold’ regions in the tissue volume being treated. This step may be done by varying the radiation dose rate of the radiation source, and may be accomplished by use of a conventional, simple linear scaling technique.

Col. 15, lines 60-67 (emphasis added). Rather, the normalization is done with respect to “each position selected,” *i.e.*, each position of the “optimized set of radiation beam positions” used for fitting in Instrument Fitting step (804).

Again, optimization is said to be accomplished at Plan Optimization step (803). As noted above, the patentees described SARP as the “preferred embodiment,” col. 8, lines 51-57, and further incorporated Webb (1989) and Webb (1991) by reference as disclosing SARP. According to the patentees, optimized treatment planning with SARP involves “dividing the radiation delivery into a large number of small beams, each of which hit the target.” Col. 12, lines 31-32; *see also* col. 8, lines 65-67 (“Existing SARP methods utilize systematic algorithms to calculate a proposed, optimized beam arrangement.”); and col. 4, line 66-col. 5, line 3 (“Further, the optimized radiation beam arrangement may be applied to the patient with a conformal radiation therapy apparatus and the proposed radiation beam arrangement may be calculated using simulated annealing radiation therapy planning methods.”). The patentees do not describe selecting or changing beam positions. Rather, the patentees rely on Webb (1989) and Webb (1991) for disclosure of optimization.

Webb (1989) does not describe “optimizing” beam positions in the sense of iteratively changing beam positions using SARP to find an “optimized” set of beam positions. Rather, Webb (1989) uses equispaced beam positions in $0-2\pi$. Webb (1989), at 1354 (“The beam orientations may be arbitrarily selected but for convenience (and to continue the imaging analogy) N_b beam orientations, equispaced in $0-2\pi$ were used.”). Webb (1989) “left to the optimisation itself to decide whether some orientations should receive low weights for all their elements (for example if that beam directly faced sensitive tissues).” *Id.* at 1354. As discussed below, Webb (1989) used sets of

various numbers of equispaced beams, *e.g.*, 32 and 128 beams, for testing optimization by the SARP algorithm against optimization by other methods.

Webb (1989) used beam weights of zero at each beam position as a starting point for the SARP process:

The technique begins with all beam weights set to zero and ‘grains’ of beam weight are offered at random to the beam elements. The term ‘grain’ implies a small quantum in the sense that the beam elemental weights which are finally arrived at comprise a large number of such quanta. At each offering the dose distribution, resulting from the current ensemble of beam elemental weights, is compared with the prescription and if the attempt at grain placement were to lead to a greater correspondence it is accepted and generally vice versa (with the important proviso discussed in the next paragraph).

Id. at 1352. That is, the weight of each beam element in each beam at each position was initially set to zero. *See also id.* at 1358 (“The initial multi-element beam profiles were taken to be empty. The resulting dose distribution was thus also empty.”). Webb (1989) explained, though, that other suitable beam weights may serve as a starting point. *See id.* at 1355 (“Other starting conditions could be used (for example uniform beam weights) since the scheme provides for both addition to and subtraction from the beam elements at each cycle of iteration.”). With that starting point, the weights of various beam elements were changed by one or more grains, and a cost function was used at each change to determine the overall cost of the resultant radiation dose distribution. If the change reduced the cost, then the change was accepted. If the change increased the cost, then the change may or may not be accepted based on a probability function. After accepting/rejecting the change, beam weights were again changed and evaluated with the cost function, and the process iterated until an optimized beam weight was reached. *See* Webb (1989), at 1355-56. Again, Webb (1989) does not describe iteratively changing beam position in that manner to arrive at what the patentees called an “optimized set of radiation beam positions.”

Furthermore, Webb (1989) added both positive and negative beam grains on a random basis. *See id.* at 1228 (“The method proceeds by adding ‘grains of beam intensity’ randomly to beam elements, so that on completion, all locations k, m have been visited many times. Grains are small elements of beam intensity, randomly positive and negative.”). Allowing both positive and negative beam weights is said to be “vital” because it allows beam weight to decrease:

Both positive and negative grains were selected. This is vital; without this feature there would be no way of decreasing a beam element value later in the iterations

when this would give a dose distribution with lower potential. The sign of the grain was selected by a random number generator so that, on average, half the grains were positive.

Id. at 1356. That is consistent with the patentee's disclosure of "changing" the beam weight as meaning "increase or decrease" in beam weight. And, as noted above, Webb (1989) suggests that an entire beam (*i.e.*, all beam elements for a beam at a given position) could be given a low weight. *See id.* at 1354. Webb (1989) thus left open the possibility that a beam weight could be decreased, presumably to zero (*e.g.*, a starting beam weight). Webb (1991) similarly describes SARP in terms of iteratively changing beam weights. But, like Webb (1989), Webb (1991) does not similarly describe iteratively changing beam position. In short, the Webb references selected a certain number of beams and spaced them equally in $0-2\pi$. The number of beams could be selected, but that selection was an input for the SARP algorithm, not a result or output of the SARP algorithm.

However, Webb (1989) does describe running the SARP algorithm several times with different beam sets, *e.g.*, sets of 32 and 128 beam distributed to determine the dose for each set, and then choosing the set that best fit the desired dose distribution. For example, in the "Brahme dose prescription" illustration (against which Webb (1989) at 1360-61 compared the results of using SARP), Webb (1989) states that "[t]he fit is degraded by reducing the number of beams from 128 to 32 *but not by much*. Rather, as we might expect a trade-off has arisen. Tumours and sensitive cold regions are better fitted when the requirement to fit normal tissue is relaxed (and vice versa). This flexibility is the new key tool of the planner who must then make the decision as to what is and what is not important structure to fit with appropriate dose envelopes." *Id.* at 1361 (emphasis in original).

Similarly, in another example, the "artificial geometry dose prescription," Webb (1989) noted the following results using different beam sets (8, 16, 32 & 128) and cost functions (FCF and LCF):

Table 1. Showing the effect on quantitation of varying the number of beams for the artificial geometry dose prescription (see figure 2).

Number of beams (N_b)	Mode	Mean and SD/ mean in tumour (%)	Mean in normal tissue/ mean in tumour	Mean in sensitive region/ mean in tumour
128	FCF	98.96 \pm 4.45	0.51 \pm 0.05	0.25 \pm 0.04
32	FCF	99.19 \pm 6.23	0.51 \pm 0.06	0.27 \pm 0.06
16	FCF	97.56 \pm 6.56	0.52 \pm 0.07	0.34 \pm 0.05
8	FCF	93.33 \pm 10.37	0.55 \pm 0.10	0.57 \pm 0.07
128	LCF	99.79 \pm 0.02	0.56 \pm 0.08	0.15 \pm 0.00
Value sought:		100 \pm 0	0.50	0.15

Webb (1989), at 1360. In that example, Webb concluded that “[f]rom this preliminary experiment it is immediately clear that small numbers of beams cannot really accommodate this prescription. However, there is not a lot of improvement in increasing the number from 32 to 128. This behavior was observed for the other dose prescriptions investigated.” *Id.* In other words, one may run SARP a number of times with different beam sets to determine optimal beam weights for each of those sets, and then select the set that provides the overall best “fit.” That is the only sense in which the Webb references describe obtaining an “optimized” set of beam positions.

As disclosed in the Webb references, therefore, the beam positions were set prior to running SARP, and those positions did not change by running SARP. If the user started with 32 equispaced beams, each having their initial weight set to zero, and then ran the SARP algorithm of Webb (1989), the beam weights may change, but the beam number and positions remained the same: 32 equispaced beams.

The Webb references, therefore, also draw a distinction between beam position and beam weight. Accuray is correct that “changing the beam weights” does not mean adding or removing beams in the sense that a new beam position is added or an existing beam position is removed. However, as noted above, a beam at given position may be given low weight, perhaps even a weight of zero. That would effectively remove the beam from the set, at least from the target’s or structure’s perspective. Or, conversely, going from a zero beam weight (*e.g.*, a starting point) to a quantifiable beam weight would effectively add a beam to the set. Thus, a beam may be added or removed in the sense that it is given some weight or no weight as a result of “changing the beam weights.”

(3) Prosecution History

As the parties note, the patentees added “wherein the proposed radiation beam arrangement is changed by changing the beam weights” to claim 25 during prosecution of the ‘283 patent. Part of the parties’ dispute involves whether the patentees disclaimed changing beam position in doing so.

In an office action dated February 16, 1999, the examiner rejected claims 26 and 27 (which ultimately issued as claim 25) as anticipated by Leber under 35 U.S.C. § 102(e). The examiner stated that “Leber shows all of the features of the instant invention including radiation (therapy) beam optimization to a target volume and minimizing radiation to a structure volume, using a computer to

modify the beam arrangement, and rejecting the new arrangement if it has a lesser correspondence to the desired radiation prescription.” JCC, Exh. 2, at 2 (emphasis added). The patentees amended original claim 26 to add “wherein the proposed radiation beam arrangement is changed by changing the beam weights.” JCC, Exh. 3, at 3. The patentees further argued that “U.S. Patent No. 5,602,892, to Leber et al. discloses a method for optimization of radiation therapy planning, including a method and apparatus for solving a numerical optimization problem that yields pencil beam fluences that will result in the optimum treatment plan using a predetermined set of gantry angles and a set of selected pencil beams for each of those gantry angles. The preferred method and apparatus for solving the numerical optimization problem comprises a computer running a new Dynamically Penalized Likelihood (DPL) iterative algorithm (Col. 3., II. 59-67, Col. 4., line 1).” *Id.* at 5.

The patentees did not, however, urge that “beam arrangement” did not include beam position, or otherwise argue that “change the proposed radiation beam arrangement” excluded changing beam position. Rather, the patentees argued that “changing the proposed radiation beam arrangement” required “changing the beam weights.” The patentees did not similarly require changing beam positions; however, they also did not clearly surrender the “beam positions” aspect of “beam arrangement.” *Cordis Corp. v. Medtronic Ave, Inc.*, 511 F.3d 1157, 1177 (Fed. Cir. 2008) (“[A]n applicant can make a binding disavowal of claim scope in the course of prosecuting the patent, through arguments made to distinguish prior art references. Such argument-based disavowals will be found, however, only if they constitute clear and unmistakable surrenders of subject matter.”). Accordingly, Best Medical is correct in that regard.

c) Recommendation

In view of the foregoing, therefore, the master recommends that the Court conclude that the term “changing the beam weights” means changing the beam intensity, including changing beam weights to zero or non-zero, but not including changing the number or position of beams.

B. Claim 29

Claim 29 is couched in means-plus-function language, and largely parallels claim 25:

25. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising:	29. An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising a computer, including:
a computer, adapted to computationally obtain a proposed radiation beam arrangement,	means for computationally obtaining a proposed radiation beam arrangement;
the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,	means for computationally changing the proposed radiation beam arrangement iteratively, wherein the means for computationally changing the proposed radiation beam arrangement includes a means for changing the beam weights;
the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and	means for incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription; and
the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.	means for rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

Initially, the parties had urged the following proposed constructions for the disputed terms of claim 29:

<u>CLAIM TERM</u>	<u>BEST MEDICAL</u>	<u>ACCURAY</u>
“An apparatus for determining an optimized radiation beam arrangement for applying radiation to a tumor target volume while minimizing radiation of a structure volume in a patient, comprising a computer, including”	See arguments concerning preamble to claim 25, above.	See arguments concerning preamble to claim 25, above.
“a means for computationally obtaining a proposed radiation beam arrangement”	<p><u>Recited Function:</u> “computationally obtaining a proposed radiation beam arrangement”</p> <p><u>Corresponding Structure:</u> “[I]ncludes a computer programmed to computationally obtaining a proposed radiation beam arrangement. The disclosed structure/algorithm is described in FIG. 2, step 803 (‘PLAN OPTIMIZATION’ and ‘BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED’), FIG. 5B (‘Simulated Annealing Parameters,’ ‘Iterations,’ ‘Start grain,’ ‘Change interval,’ ‘kT₀/beam,’ ‘End grain,’ ‘End threshold’ and ‘Revert to Default’), and the descriptions set forth at Col. 12:27-34; Col. 8:61-67; Col. 9:52-59; Col. 10:43-53, and equivalents thereof.”</p>	<p><u>Recited Function:</u> “computationally obtaining a proposed radiation beam arrangement”</p> <p><u>Corresponding Structure:</u> “The specific computer configured to run the simulated annealing (‘SARP’) algorithm.”</p>

<u>CLAIM TERM</u>	<u>BEST MEDICAL</u>	<u>ACCURAY</u>
“means for computationally changing the proposed radiation beam arrangement iteratively, wherein the means for computationally changing the proposed radiation beam arrangement includes”	<p><u>Recited Function:</u> “computationally changing the proposed radiation beam arrangement iteratively”</p> <p><u>Corresponding Structure:</u> “[I]ncludes a computer programmed to computationally change the proposed radiation beam arrangement iteratively. The disclosed structure/algorithm is described in FIG. 2, step 803 (‘PLAN OPTIMIZATION’ and ‘BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED’), FIG. 5B (‘Stimulated Annealing Parameters’ and ‘Iterations’), and the description set forth at Col. 9:33-48; and Col. 12:27-47, and equivalents thereof.”</p>	<p><u>Recited Function:</u> “computationally changing the proposed radiation beam arrangement iteratively”</p> <p><u>Corresponding Structure:</u> “The specific computer configured to run the simulated annealing (‘SARP’) algorithm.”</p>
“means for changing the beam weights”	<p><u>Recited Function:</u> “changing the beam weights”</p> <p><u>Corresponding Structure:</u> “[I]ncludes a computer programmed to change the beam weights. The disclosed structure/algorithm is described In fig 2, STEP 803 (‘PLAN OPTIMIZATION’ and ‘BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED’), FIG. 5B (‘Stimulated Annealing Parameters,’ ‘Iterations,’ ‘Start grain,’ ‘Change interval,’ ‘kT₀/beam,’ ‘End grain’ and ‘End threshold’), FIGS. 6A and 6B, and the descriptions set forth at Col. 12:27-34; Col.</p>	<p><u>Recited Function:</u> “changing the beam weights”</p> <p><u>Corresponding Structure:</u> “The specific computer configured to run the simulated annealing (‘SARP’) algorithm.”</p>

<u>CLAIM TERM</u>	<u>BEST MEDICAL</u>	<u>ACCURAY</u>
	13:43-52, Col. 9:13-28; and Col. 14:44 - 14:47, and equivalents thereof.)”	
“means for incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription”	<p><u>Recited Function:</u> “incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription”</p> <p><u>Corresponding Structure:</u> “[I]ncludes a computer programmed to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription. The disclosed structure/algorithm is $C_{Total} = C_S + C_T$, where C_S is the sum of the costs calculated for each structure zone and C_T is the sum of the costs calculated for each target zone, as described in Col. 13:1-14:10 and Col. 10:31-34. <i>See also</i> Col. 4:13-5:8; Col. 9:28-12:67; and Col. 8:61-67. <i>See also</i> FIG. 2, step 802 (‘PRESCRIPTION PANEL’ and ‘DOSE PRESCRIPTION TO STRUCTURES SPECIFIED’) and step 803 (‘PLAN OPTIMIZATION’ and ‘BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED’), FIG. 3</p>	<p><u>Recited Function:</u> “incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription”</p> <p><u>Corresponding Structure:</u> “The specific computer configured to run the simulated annealing (‘SARP’) algorithm.”</p>

<u>CLAIM TERM</u>	<u>BEST MEDICAL</u>	<u>ACCURAY</u>
	(PERCENT VOLUME vs. DOSE (Gy) curve) and FIG. 4 (PERCENT VOLUME v. DOSE (Gy) curve), FIG. 5A ('Target' entries and 'Sensitive Structure' entries) and ('Review the prescription, planning parameters and maximum dose to non-target structures. If all are correct, approve the prescription') and FIG. 5B ((Percent) Volume vs. Dose (Gy) curve and 'Simulated Annealing Parameters'). <i>See also</i> Col. 10:43-12:26."	
<p>"means for rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement"</p>	<p><u>Recited Function:</u> "rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam"</p> <p><u>Corresponding Structure:</u> "[I]ncludes a computer programmed to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accept the change of the proposed radiation beam arrangement if the change of the proposed</p>	<p><u>Recited Function:</u> "rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam"</p> <p><u>Corresponding Structure:</u> "The specific computer configured to run the simulated annealing ('SARP') algorithm."</p>

<u>CLAIM TERM</u>	<u>BEST MEDICAL</u>	<u>ACCURAY</u>
	radiation beam leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam. The disclosed structure/algorithm is described in Col. 13:40-14:10 and Col. 14:47-58. <i>See also</i> Col. 9:33-45 and Col. 12:27-34. <i>See also</i> FIG. 2, step 803 ('PLAN OPTIMIZATION' and 'BEAM POSITION AND STRENGTH OPTIMIZATION PERFORMED'), FIG. 5A ('Approve Prescription and Compute Plan') and FIG. 5B ('Plan Optimization,' 'User Defined' and 'Simulated Annealing Parameters'). <i>See also</i> Col. Col. [sic] 10:31-34 and 10:57-12:26."	

JCC at 96-139.

1. Discussion

The parties agree that these terms are means-plus-function terms governed by 35 U.S.C. § 112(6), and the master agrees. *See* JCC at 104; *see* Best Medical Brief at 23; *see* Accuray Brief at 50. The limitations each use the term "means," thus, § 112(6) presumptively applies. The words "means for" are followed by the function language, for example, "computationally obtaining a proposed radiation beam arrangement." Lastly, there is no structure recited in the claims for performing the recited functions. As noted above, means-plus-function limitations are construed differently than non-means-plus-function limitations. The parties do not dispute the recited functions.

During the *Markman* Hearing, Best Medical explained that the words "Includes a computer" in each of its proposed corresponding structure meant that the corresponding structure could include more than one computer. *See Markman* Tr. at 102-103. Best Medical stipulated that these words in its proposed corresponding structure meant "one or more computers." *See id.*

Best Medical subsequently agreed that the corresponding structure should be “one or more computers configured to run the simulated annealing SARP algorithm,” plus the equivalents provided for under the statute. *See id.* Accuray also agreed to that construction. *See id.* at 156.

The specification discloses one or more computers programmed with SARP as the preferred iterative optimization method, and there is no dispute that “one or more computers configured to run SARP” is the “corresponding structure” that is “clearly linked” to the recited functions. Col. 9, lines 45-48 (“Ultimately, the SARP method will produce an optimized treatment plan, based on the treatment objectives as expressed by the cost function incorporated in the SARP algorithm.”); col. 9, lines 59-64 (“The optimization method may be carried out using conventional equipment, including a conventional linear accelerator (‘LINAC’) 300, as shown in FIG. 1, having a rotatable gantry, a conventional computer or set of computers, and plan optimization software, which utilizes the optimization method of the present invention.”); *see Medtronic, Inc.*, 248 F.3d at 1303, 1311 (quotes omitted) (“Structure disclosed in the specification is ‘corresponding’ structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim,” *quoting B. Braun Med., Inc. v. Abbott Labs*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)).

One thing remains, however. Claim 29 requires use of a cost function, which SARP also requires. *See, e.g.*, ‘283 patent, col. 9, lines 45-48 (“Ultimately, the SARP method will produce an optimized treatment plan, based on the treatment objectives as expressed by the cost function incorporated in the SARP algorithm.”). Claim 29 further requires that the cost function use partial volume data. The only cost function algorithm disclosed in the ‘283 patent as using partial volume data is the cost function set forth in column 13, lines 4-39. Accordingly, the “corresponding structure” includes that cost function.

2. Recommendation

In view of the foregoing, therefore, the master recommends that the Court construe the “means” limitations of claim 29 as follows:

<u>Element</u>	<u>Recited Function</u>
“means for computationally obtaining a proposed radiation beam arrangement”	“computationally obtaining a proposed radiation beam arrangement”
“means for computationally changing the proposed radiation beam arrangement iteratively, wherein the means for computationally changing the proposed radiation beam arrangement includes a means for changing the beam weights”	“computationally changing the proposed radiation beam arrangement iteratively, wherein the means for computationally changing the proposed radiation beam arrangement includes a means for changing the beam weights”
“means for incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription”	“incorporating a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a predetermined desired dose prescription”
“means for rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement”	“rejecting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and accepting the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement”

The “corresponding structure” for each of these recited functions is one or more computers running the SARP algorithm and the cost function set forth in column 13, lines 4-39.

Under the terms of § 112(6), “such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.”

V.

Level of Ordinary Skill in the Art

A. The Parties' Arguments

Accuray argues that “[t]he level of skill in the field of radiation therapy planning, and particularly optimization in the mid-1990’s was very high.” Accuray’s Response at 18. Specifically, Accuray urges that one of skill in the art “would have had a PhD in physics, medical physics or a related science, at least five years of practical experience in radiation treatment planning, and at least several years of research in treatment plan optimization.” *Id.*

Best Medical contends that Accuray’s definition of the level of skill in the art is “overly restrictive and seems designed to only include Accuray’s expert.” Best Medical’s Reply at 33. Best Medical argues that:

Accuray’s definition ignores those with a master’s level degree in a relevant field such as physics, regardless of the years of practical experience, and would exclude anyone regardless of degree or practical experience, if he or she did not have research experience. In fact, it would exclude experienced physicians with a M.D. but not a Ph.D.

Id. According to Best Medical, the level of skill in the art would include “a Qualified Medical Physicist” (a person who has “earned a master’s or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university”) or “other health care practitioners, such as medical doctors or clinicians with several years of experience in radiation treatment planning.” *Id.*

B. Discussion

According to the Federal Circuit, “[f]actors that may be considered in determining the level of skill in the art include: (1) the educational level of the inventors; (2) the type of problems encountered in the art; (3) prior art solutions to those problems; (4) the rapidity with which innovations are made; (5) sophistication of the technology; and (6) education level of active workers in the field.” *Env’tl Designs, Ltd. v. Union Oil Co. of California*, 713 F.2d 693, 696 (Fed. Cir. 1983). “These factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art.” *Daiichi Sankyo Co. Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

The ‘283 patent provides some evidence of the sort of person who would be implementing the subject matter disclosed, namely, “[p]hysicians and those skilled in the art of radiation dosimetry

are familiar with CDVH curves 100, 200 * * *.” Col. 10, lines 39-41 (emphasis added). That is apparently because such skill is required to account for the effect of radiation on different organs of the human body. *See* col. 13, lines 53-59 (“By assigning different weights to different zones of the CDVH curves, different results can be obtained. Therefore, the weights are incorporated into the software with an outcome in mind, and the user must understand what kind of results the assigned weights will produce. One skilled in the art will be able to choose the desired weights without undue experimentation to achieve a desired outcome in the system.”); col. 15, lines 16-20 (“The weights can then be chosen through experience and minimal experimentation by one skilled in the art so that the following treatment objectives can be met in a desired application depending on the aggressiveness of the treatment plan: * * *.”). Clearly, a medically-trained person (including M.D.s) would be required to use the system disclosed in connection with an actual patient, and some clinical expertise appears to be required. *See* col. 14, lines 7-10 (“The actual weights assigned are based upon clinical experience by one skilled in the art. These weights can then be programmed into the system so they can be used repeatedly to produce a desired outcome.”). The patentees do not suggest that research experience is required.

From a survey of the literature provided by the parties, the “ordinary” level of skill in the art appears to be quite high; however, a PhD skill level does not appear to be required. Dr. Webb apparently relied on at least one person without a doctorate to help review his articles on SARP. *See* Webb (1989), at 1368 (“I am grateful to Drs A Nahum, W Swindell and M Rosenbloom and Mr D Convery for stimulating discussion.” (emphasis added)); Webb (1991), at 1236 (“I should like to thank Dr. A Nahum and Mr D Convery for comments on this manuscript.” (emphasis added)); and Webb 3D, at 1222 (“I am very grateful to Drs A Nahum, W Swindell and Mr D Convery for comments on this manuscript.”). Presumably, Mr. Convery was sufficiently skilled without a Ph.D. (or M.D.) that Dr. Webb mentioned him on at least three of his articles. Indeed, Mr. Convery is named as author in his own right (along with co-author Rosenbloom) of one reference cited on the ‘283 patent as prior art (“The Generation of Intensity-Modulated Fields for Conformal Radiotherapy by Dynamic Collimation,” D. Convery and M. E. Rosenbloom; *Phys. Med. Biol.*, 1992, vol. 37, No. 6, pp. 1359-1374.”). Furthermore, a roughly contemporaneous treatise, *The Theory and Practice of Intensity Modulated Radiation Therapy* (Adv. Med. Pub. 1997), includes an author lacking a Ph.D. or M.D. *See* Accuray’s Extrinsic Evidence, Exh. 3 [Dkt. 139-3] (listing author “Bruce H.

Curran, ME, MS”). Thus, the master is reluctant to draw a bright line by requiring that an artisan have a Ph.D.

Also, the specification states that several elements described in the ‘283 patent specification are known in the art, for example LINACs, the simulated annealing method, CT scanning, MRI techniques, image normalization, patient fixation device geometry, conventional optimization techniques, and the Three-Dimensional Modified Path Length technique. *See* col. 1, lines 28-31; col. 3, lines 21-22; col. 8, lines 61-65; col. 10, lines 1-24; col. 12, lines 32-47; col. 13, lines 46-47; col. 16, lines 1-12. There is no evidence of record that a Ph.D. would be required to implement those well-known techniques and hardware.

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Best Medical's proposal that an artisan would be a Qualified Medical Physicist ("QMP") appears based on a definition created in November of 2011:⁵

The screenshot shows the AAPM website interface. The header includes the AAPM logo, the text "The American Association of Physicists in Medicine", and a banner for the "54th Annual Meeting & Exhibition" from July 29 to August 2 in Charlotte, NC. Navigation links for Home, Directory, Career Services, Continuing Education, and RSS are present. A search bar and font size controls are also visible.

The left sidebar contains a "Login" button and a menu with categories: AAPM (Join the AAPM, Staff Contacts, Expense Claims, Mission), Policies & Procedures (Association Governance, Committees, Committee Classifieds, Individual Appointments, History & Heritage, Chapters), Public & Media, International, Medical Physicist, Members, Current & Prospective Students, Meetings, Education, Government Affairs, Publications, Career Services, Corporate Affiliates, Links of Interest, Advertising Opportunities, CT Protocols, Image Gallery, and Quantitative Imaging.

The main content area is titled "Professional/Education/Science Policies". It features a table with the following data:

POLICY NUMBER	POLICY NAME	POLICY DATE	SUNSET DATE
PP 1-H	Definition of A Qualified Medical Physicist	11/30/2011	12/31/2016

Below the table, the "Policy source" and "Policy text" sections are displayed. The policy text defines a Qualified Medical Physicist (QMP) and lists four subfields of medical physics:

1. Therapeutic Medical Physics
2. Diagnostic Medical Physics
3. Nuclear Medical Physics
4. Medical Health Physics

The text further states that the scope of practice for each subfield is defined in the AAPM Professional Policy 17 "Scope of Practice of Clinical Medical Physics". It then lists the credentials required for a QMP:

1. Has earned a master's or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and
2. Has been granted certification in the specific subfield(s) of medical physics with its associated medical health physics aspects by an appropriate national certifying body and abides by the certifying body's requirements for continuing education.

The following national certifying bodies have been deemed appropriate:

1. **For the subfield of Therapeutic Medical Physics**, certification by:
 - The American Board of Radiology; or
 - The American Board of Medical Physics; or
 - The Canadian College of Physicists in Medicine.
2. **For the subfield of Diagnostic Medical Physics**, certification by:
 - The American Board of Radiology; or
 - The American Board of Medical Physics; or
 - The Canadian College of Physicists in Medicine.
3. **For the subfield of Nuclear Medical Physics**, certification by:
 - The American Board of Radiology; or
 - The American Board of Medical Physics; or
 - The Canadian College of Physicists in Medicine; or
 - The American Board of Science in Nuclear Medicine.
4. **For the subfield of Medical Health Physics**, certification by:
 - The American Board of Medical Physics; or
 - The American Board of Health Physics including a minimum of three years relevant experience in the subfield of medical health physics.

A footnote at the bottom states: "Previous certification categories in medical physics included radiological physics, therapeutic radiological physics, medical nuclear physics, diagnostic radiological physics and diagnostic imaging physics."

A link at the bottom of the page reads "Return to Professional/Education/Science Policies".

⁵ <http://www.aapm.org/org/policies/details.asp?id=316&type=PP>.

The definition of QMP goes beyond that noted by Best Medical: a QMP further requires some sort of certification in a specific subfield of medical physics. Best Medical offers no evidence of QMP qualification in 1996. Nevertheless, the parties at least agree that physics, medical physics, and related fields are among those fields in which a person of ordinary skill in the art would be trained.

C. Recommendation

In view of the foregoing, therefore, the master recommends that the Court conclude that a person of ordinary skill in the art is an individual who has earned a master's or doctoral degree in radiation dosimetry, physics, medical physics, medicine, or equivalent disciplines, and has several years of clinical experience in radiation treatment planning.

VI. Objections to Extrinsic Evidence

Each party objects to extrinsic evidence proffered by the other. Best Medical objects to a number of technical references and to the testimony of Accuray's expert, Dr. Rosen. Accuray objects to various dictionaries relied on by Best Medical.

A. The Parties' Contentions

1. Best Medical's Arguments

Best Medical objects to Accuray's offer of the Declaration of Dr. Isaac I. Rosen ("Rosen Declaration," Accuray's Extrinsic Evidence) and accompanying exhibits as extrinsic evidence "[p]ursuant to LPR 4.3 * * * on the basis that they are irrelevant to the issue of claim construction and not part of the intrinsic record." Best Medical's Reply at 33. Best Medical "further objects to Accuray's use of the Rosen Declaration and accompanying exhibits as extrinsic evidence to the extent that Accuray seeks to introduce them without providing the context in which they were created." *Id.* at 33-34.

Best Medical argues that the Rosen Declaration "does not offer unbiased testimony that seeks to shed light on claim terms and phrases having special meaning in the technical field of radiation treatment planning software, but instead reads like a legal brief having the sole intent of re-writing the disputed claim terms in accordance with Accuray's proposed construction." *Id.* at 3. Best Medical argues that the Rosen Declaration merely "repeats Accuray's proposed construction and then concludes each recitation with the phrase: 'I agree with Accuray's construction, and it is

my opinion that one skilled in the art would interpret this phrase in that way, in view of the specification, the file history and the general knowledge of those skilled in the art at the time the '283 patent was filed.” *Id.* Best Medical contends that “the Rosen Declaration is nothing more than a compilation of legal arguments, which Accuray apparently hopes will be given more weight because they are made in an ‘expert’ declaration.” *Id.* Best Medical argues that “[t]he Rosen Declaration is the exact type of biased, litigation generated testimony that the Federal Circuit warned about in *Phillips*.” *Id.* Best Medical urges that “any assertions by an expert as to the definition of a claim term that is at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history should be disregarded.” *Id.* at 4. Thus, Best Medical argues, “Accuray should not be permitted to use the Rosen Declaration and other irrelevant, extrinsic evidence to reconceptualize the claims.” *Id.*

Best Medical also argues that under *Daubert v. Merrill Dow Pharms, Inc.*, 509 U.S. 579 (1993) and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), the court should act as a “gatekeeper,” and exclude the Rosen Declaration. *Id.* at 4, 7. Best Medical urges that Rosen only “offers his opinion on the *correctness* of Accuray’s construction of the claims and of the patent at issue,” that “Rosen acknowledges that he is being compensated by Accuray at the hourly rate of \$350 per hour, plus expenses,” and that Rosen is employed by an Accuray treatment center for Accuray’s other product line, Tomography. *Id.* at 5 n.3. Best Medical argues that the Rosen Declaration attempts to “usurp the role of the Special Master and the Court in determining the proper construction to be given to the disputed claim terms by rewriting those terms,” and that “[s]uch extrinsic evidence should be stricken as biased and unhelpful to the Court in making its decision on claims [*sic*] construction.” *Id.* Best Medical argues that “[a] full 22 pages of the Rosen Declaration represents a tutorial on the area of radiation therapy. The remainder of the Declaration consists of Rosen affirming the construction given by Accuray to the disputed claim terms.” *Id.* at 6.

Best Medical urges that while “Rosen claims to base his opinions on his ‘view of the specification, the file history, and the general knowledge of those skilled in the art at the time the ‘283 patent was filed[,]’ * * * what he does is to provide his opinions concerning other inventions by the inventor, Dr. Carol, referred to as Peacock and Corvus, and concludes that the ‘283 Patent has the same alleged limitations as those. See Rosen Declaration, ¶¶ 109-114. However, nowhere in the patent specification or claims is there any reference to either Peacock or Corvus. Evidence of those inventions can shed no light on what was intended by the patent at issue and its particular claims.

Indeed, the absence of such references supports Best Medical's interpretation that the claims are not so limited." *Id.* at 7.

Best Medical also argues that the technical articles relied upon by Rosen and Accuray should be disregarded. *Id.* at 9. Best Medical argues that Dr. Rosen "cannot demonstrate how those relate to the claims at issue other than his opinion that they do. It is the equivalent of double hearsay." *Id.* "In essence, [Rosen] is saying, 'here is what someone else said and this is what it means.' The Court should disregard those portions of the Declaration Rosen [*sic*] as biased, irrelevant and unhelpful." *Id.* In addition, Best Medical argues that "[w]hile dictionary definitions are routinely admitted and considered as being useful for the purpose of claim construction, the technical articles and other literature relied upon by Rosen and Accuray are irrelevant and inadmissible extrinsic evidence." *Id.* (citations omitted).

Best Medical objects to the below-listed evidence "on the basis that they are irrelevant to the issue of claim construction and not part of the intrinsic record, and to the extent that any were published after the earliest effective date of the filing of the '283 Patent:"

Document No. 139-1 — Bortfeld et al., 'Optimization of beam orientations in radiation therapy: some theoretical considerations', *Phys. Med. Biol.* 38 (1993) 291-304.

Document No. 139-2 — Carol, 'PeacockTM: A System for Planning and Rotational Delivery of Intensity-Modulated Fields', *International Journal of Imaging Systems and Technology*, Vol. 6, 56-61 (1995).

Document No. 139-3 — Carol, 'Chapter 2 — IMRT: Where We Are Today', 'The Theory and Practice of Intensity Modulated Radiation Therapy, Proceedings of the 1st NOMOS IMRT Workshop, Durango, Colorado, 17-36, 1997.

Document No. 139-4 — Carol, 'Chapter 17 — Where We Go From Here: One Person's Vision', 'The Theory and Practice of Intensity Modulated Radiation Therapy, Proceedings of the 1st NOMOS IMRT Workshop, Durango, Colorado, 17-36, 1997.

Document No. 139-5 — Carol et al., 'The Development Of A Clinically Intuitive Approach To Inverse Treatment Planning: Partial Volume Prescription And Area Cost Function', Proceedings of the XIIth International Conference on the Use of Computers in Radiation Therapy, Salt Lake City Utah, 317-319, 1997.

Document No. 139-6 — Deasy, 'Multiple local minima in radiotherapy optimization problems with dose-volume constraints', *Med. Phys.*, 24(7), 1157-1161, July 1997.

Document No. 139-7 — Källman et al., 'An algorithm for maximizing the probability of complication-free tumour control in radiation therapy', *Phys. Med. Biol.*, 1992, Vol. 37, No. 4, 871-890.

Document No. 139-8 — Kirkpatrick et al., 'Optimization by Simulated Annealing', *Science*, 13 May 1983, Volume 220, Number 4598, 671-680.

Document No. 139-9 — Langer et al., 'A generic genetic algorithm for generating beam weights', *Med. Phys.*, 23(6), June 1996, 965-971.

Document No. 139-10 — Langer et al., 'A comparison of mixed integer programming and fast simulated annealing for optimizing beam weights in radiation therapy', *Med Phys.* 23(6), June 1996, 957-964.

Document No. 139-11 — Mageras et al., 'Application of fast simulated annealing to optimization of conformal radiation treatments', *Med. Phys.* 20(3), May/June 1993, 639-647.

Document No. 139-12 — Morrill et al., 'Treatment planning optimization using constrained simulated annealing', *Phys. Med Biol.*, 1991, Vol. 36, No. 10, 1341-1361.

Document No. 139-13 — Morrill et al., 'Constrained simulated annealing for optimized radiation therapy treatment planning', *Computer Methods and Programs in Biomedicine*, 33 (1990) 135-144.

Document No. 139-14 — Niemierko, 'Random Search Algorithm (RONSC) for Optimization of Radiation Therapy with Both Physical and Biological End Points and Constraints', *Int. J. Radiation Oncology Biol. Phys.*, Vol. 23, 1992, 89-98.

Document No. 139-15 — Rosen et al., 'Comparison of Simulated Annealing Algorithms for Conformal Therapy Treatment Planning', *Int. J. Radiation Oncology Biol. Phys.*, Vol. 33, No. 5, 1091-1099, 1995.

Document No. 139-16 — Rosen et al., 'Treatment plan optimization using linear programming', *Med. Phys.* 18(2), March/April 1991, 141-152.

Document No. 139-17 — Spirou et al., 'A gradient inverse planning algorithm with dose-volume constraints', *Med Phys.* 25(3), March 1998, 321-333.

Document No. 139-18 — Szu et al., 'Fast Simulated Annealing', *Physics Letters A*, Volume 122, Number 3,4, 8 June 1987, 157-162.

Document No. 139-19 — Morrill et al., 'Very Fast Simulated Reannealing in Radiation Therapy Treatment Plan Optimization', *Int. J. Radiation Oncology Biol. Phys.*, Vol. 31, No. 1, 179-188, 1995.

Document No. 139-21 — Webb, 'Optimization by simulated annealing of three-dimensional, conformal treatment planning for radiation fields defined by a multileaf collimator: II. Inclusion of two-dimensional modulation of the x-ray intensity', *Phys. Med. Biol.*, 1992, Vol. 37, No. 8, 1689-1704.

Document No. 139-22 — Webb, 'Chapter 4 — Inverse Planning for IMRT: The Role of Simulated Annealing', *The Theory and Practice of Intensity Modulated Radiation Therapy*, Proceedings of the 1st NOMOS IMRT Workshop, Durango, Colorado, 51-73, 1997.

Document No. 139-23 — Yu, 'Multiobjective decision theory for computational optimization in radiation therapy', *Med Phys.* 24(9), September 1997, 1445-1454.

Id. at 34-36. Best Medical “further objects to Accuray’s use of the above-listed references as extrinsic evidence to the extent that Accuray seeks to introduce them without providing the context in which they were created.” *Id.* at 36. Best Medical also “requests that the Special Master and Court consider the above objections in deciding whether to receive the extrinsic evidence identified by Accuray. Even if the extrinsic evidence is received, Best Medical respectfully submits that such extrinsic evidence should be given minimal weight, if any, in construing the disputed claim terms.” *Id.* at 36.

In a footnote, Best Medical adds:

Curiously, with regard to its proposed construction limiting the claim to SARP, one of the physicians who uses the CyberKnife Treatment Planning System® has described the CyberKnife Planning System as follows: ‘All CK [CyberKnife] planning is inverse planning, meaning they can specify the dose and that the computer chooses the beams, rather than choosing the beams and letting the computer tell you the resulting dose. The exact algorithm used is probably not particularly important.’ (emphasis added) Statement of Clinton A. Medberry, III, M.D., on an Accuray patient forum dated September 25, 2011, attached hereto as Exhibit 2 at p. 1. Presumably, that would include the SARP algorithm.

Id. at 6 n.5.

Accuray argues that Best Medical “demonstrates through its briefs that it does not understand its own patent, does not understand the underlying technology, and does not even attempt to try. [Best Medical’s] version of claim construction is a mechanistic, barely linguistic exercise of defining isolated claim terms by using Webster’s dictionary.” Accuray’s Sur-Reply at 1. Accuray urges that Best Medical’s “isolated constructions do not explain what the inventor invented. [Best Medical] apparently does not know because it provides no explanation that would help the court understand the claims. [Best Medical] does not even address the background of the technology. To explain a complex, cutting edge field that saves lives, [Best Medical] relies only on dictionaries.” *Id.*

Regarding what Accuray calls Best Medical’s criticism of Accuray’s use of extrinsic evidence to educate the court, Accuray asks “how can the court educate itself to the level of one of skill in the art without the help of relevant technical articles and an expert who was working in the field at the time the patent application was filed?” *Id.* Accuray argues that “[t]he ‘283 patent cannot be interpreted from the layperson’s perspective – it involves a specialized technology that requires at a minimum, an understanding of complex optimization algorithms, radiation physics, and treatment

delivery.” *Id.* at 1-2. Accuray argues that Best Medical “does not engage on the technology at all. With the absence of any discussion on the technology in [Best Medical’s] opening or reply claim construction briefs, Accuray’s explanation of the background of the technology and the state of the art is undisputed.” *Id.* at 2.

Regarding Best Medical’s arguments concerning Dr. Rosen, Accuray argues that Best Medical:

must recognize that if Dr. Rosen is not a proper expert, no one is. Dr. Rosen has the requisite credentials; was working in the field from 1975 to the present; knew the principal inventor, Mark Carol, and Dr. Webb; and participated in the Durango NOMOS workshop in 1996, at which Dr. Carol disclosed his work. Nor does [Best Medical] disagree with any particular point of Dr. Rosen’s substantive discussion of the technical field of radiation therapy planning. [Best Medical] admits that ‘a full 22 pages of the Rosen Declaration represents a tutorial on the area of radiation therapy,’ which is precisely the intended purpose of his declaration and for such expert testimony. Although [Best Medical] views the tutorial with suspicion, it has countered with no expert of its own, nor has it made substantive objections with regard to Dr. Rosen’s explanation of the background of the technology.

Id. With regard to the technical articles cited by Accuray and Dr. Rosen, Accuray argues that:

[t]hese technical articles, including articles by Dr. Webb, Dr. Carol, and other experts in the field, were published contemporaneous with or earlier than the filing date of the patent, and are evidence of the state of the art. Significantly, [Best Medical] ignores the Webb articles incorporated by reference in the ‘283 patent. The Court should ask [Best Medical] why it ignores Webb. The Webb articles are the sole disclosure of how the only optimization algorithm disclosed in the patent (SARP) generates and changes ‘proposed radiation beam arrangements.’ Moreover, Webb’s work, which was never patented and was publicly available, was the foundation on which the principal inventor, Dr. Mark Carol, built the NOMOS radiation therapy planning technology – as both Dr. Carol and Dr. Webb agree.

Id. at 2-3.

Accuray states that Best Medical “argues that Accuray’s proposed claim constructions are based only on extrinsic evidence, but nothing could be further from the truth. Accuray has used the methodology set forth in *Phillips*, focusing on the claims and the written description, as the primary source of claim meaning.” *Id.* at 3. Accuray argues that it “uses extrinsic evidence only to complement the intrinsic evidence: to explain the background of this complex technology, the state of the art, and how one of skill in the art would have understood the patent at the time the ‘283

application was filed.” *Id.* Accuray argues that Best Medical “never engages in substantive arguments about why Accuray’s proposed constructions are wrong. It does not use the specification to show that the technology is other than Accuray says it is.” *Id.*

Accuray also urges that Best Medical:

has given no thought to what happens if it is successful in obtaining its ‘plain meaning’ claim construction. Its construction is so broad that its claims will be rendered invalid in view of virtually every prior art reference that addresses radiation treatment planning. Clearly, the Patent Office would never have allowed such a patent to issue with the construction proposed by [Best Medical]. Given the choice between two constructions – a construction so broad it renders the claim invalid and a narrower construction fully supported by the specification, the technical articles incorporated by reference, and the inventor’s contemporaneous disclosure of the invention – the Court must choose the second construction. Only Accuray’s construction is consonant with ‘what the inventor actually invented.’

Id. at 4.

Accuray urges that Best Medical’s “only attempt to rebut the Rosen Declaration is based on a random posting on a message board, purportedly from a doctor, stating that, because all CK planning is inverse planning...the exact algorithm used is probably not particularly important,” citing to Best Medical’s Reply at 6 n.5. *Id.* Accuray states that Best Medical “is apparently arguing that Accuray’s proposed construction limiting the claims to SARP would not preclude infringement by the CyberKnife because the CyberKnife could conceivably use SARP rather than the algorithms it actually does use. [Best Medical] infers from this comment that “presumably, that would include the SARP algorithm.” *Id.* Accuray argues that Best Medical “wields the random musings of someone on a message board as if it were the statement of a pseudo-expert.” *Id.* Accuray argues that the message board statement “is an out-of-court statement offered for its truth by someone who is not subject to cross-examination. The message board has not been established to be a reliable source, and there is no way to test the reliability of the statement, or whether the author has the experience to understand the algorithms Accuray uses. Infringement cannot be based on such random musings.” *Id.*

Accuray argues that Best Medical’s “insinuations” that Dr. Rosen is not a proper expert should be rejected. *Id.* at 5. Accuray argues that Best Medical “does not – and cannot – attempt to disqualify Dr. Rosen as an expert based upon his credentials.” *Id.* Accuray summarizes Rosen’s

credentials and urges that “Dr. Rosen is clearly qualified to serve as an expert on the technology at issue in this case. Indeed, he lived through much of the history of this technology and his work helped to shape it into what it is today. If Dr. Rosen were deemed to be unqualified to serve as an expert in this case, no one would qualify.” *Id.* at 6.

Accuray argues that “Dr. Rosen’s testimony provides background and context for Accuray’s constructions. Notwithstanding [Best Medical’s] efforts to trivialize the field of the invention, radiation physics is a highly specialized area requiring an advanced degree in physics or the equivalent and many years of advanced training. The technology is not intuitive, nor can it be understood in any meaningful way by resort to English language dictionaries. [Best Medical] concedes that the majority of the Rosen Declaration ‘represents a tutorial on the area of radiation therapy.’ (Doc. No. 142 at p. 6) Presenting a technical tutorial to educate the Court is appropriate given the complexity of the technology at issue, and is permissible under this Court’s Local Rules. *See* LPR 4.3 (permitting parties to present expert testimony in support of proposed claim constructions). The Special Master’s Claim Construction Hearing Order also provides for expert testimony on claim construction in this case.” *Id.* at 7. Accuray also argues that “[w]hile Dr. Rosen’s testimony may not support the English language dictionary definitions advanced by [Best Medical], it is entirely consistent with the ‘283 patent specification, the Webb articles (incorporated by reference into the specification at Col. 12:34-45), the file history, and the general knowledge and state of the art at the time the ‘283 patent was filed.” *Id.* at 7-8. Accuray argues that the purpose of Dr. Rosen’s declaration is “to provide background on the complex technology at issue in this case and to assist the Court in understanding the technical aspects of the patent as the skilled artisan would understand them.” *Id.* at 8. Accuray argues that “the Court can look to expert testimony in claim construction if it is considered in the context of the intrinsic record, as it is here.” *Id.* at 9. Accuray argues that “Dr. Rosen’s testimony is fully consistent with and supported by the specification” and “Dr. Rosen’s discussion of the patent claims is likewise supported by the specification, Dr. Webb’s articles, and Dr. Carol’s contemporaneous publications.” *Id.* at 10.

Regarding Best Medical’s objections to “Dr. Rosen’s reference to NOMOS’s ‘Corvus’ treatment planning system and its predecessor, the ‘Peacock’ system,” Accuray argues that, while Best Medical “argues that [these] systems are irrelevant to the patents-in-suit,” “[e]arlier in this case, however, [Best Medical] took a very different position, and represented that the Corvus system

embodies the claimed invention of the ‘283 patent.” *Id.* at 11. Accuray argues that “[t]he figures in the ‘283 patent refer to NOMOS’s Peacock and Corvus technology.” *Id.* at 12.

Accuray also argues that Best Medical’s objections to Dr. Rosen’s declaration as litigation generated and biased are not well founded. *Id.* at 13. Accuray argues that “[b]y their nature, expert testimony is ‘litigation generated.’ The fact that testimony is provided during the course of litigation is not a basis for excluding it.” *Id.* Accuray notes that “the only ‘evidence’ that [Best Medical] relies on in making its bias accusations is that Dr. Rosen is being compensated for his work on this litigation at a rate of \$350 per hour and that Dr. Rosen works for the Methodist Hospital in Houston, which owns a ‘TomoTherapy’ system.” *Id.* Accuray argues that “[e]xpert witnesses are routinely compensated for their work in litigation,” and “Methodist Hospital also owns equipment sold by a number of Accuray’s competitors.” *Id.* at 14. Thus, Accuray argues that Best Medical’s “vague innuendos do not provide any basis to exclude his testimony.” *Id.*

As for the Webb articles, Accuray argues that “Dr. Webb’s articles are not all ‘irrelevant,’ nor are they ‘extrinsic publications.’” *Id.* Accuray argues that “Dr. Webb’s articles are incorporated by reference into the ‘283 patent specification and listed on the face of the patent. As such, they are part of the *intrinsic* record. Further, Dr. Webb’s articles provide the *only* description of an optimization algorithm in the ‘283 patent.” *Id.* (Accuray’s emphasis). Accuray argues that Best Medical’s “suggestion that Accuray ‘cannot tie [Dr. Webb’s articles] to the patent or the claim language’ – when these articles are cited in the file history of the patent and incorporated by reference in the specification itself – is completely disingenuous and must be rejected.” *Id.* at 15.

Regarding Dr. Carol’s contemporaneous publications, Accuray argues that “[f]ar from ‘irrelevant,’ Dr. Carol’s publications explain the background of IMRT and state of the art at the time. Dr. Carol’s publications also explain treatment planning optimization and in the Peacock system * * *. In fact, Dr. Carol’s May, 1995 article describes a treatment planning system that is virtually identical to the subject matter of the ‘283 patent, and includes nearly every element of claims 25 and 29.” *Id.*

Regarding the remaining articles cited by Accuray and Dr. Rosen, Accuray argues that “[e]ach of these articles are relevant to show, at a minimum, the background and state of the art of the time the ‘283 patent was filed.” *Id.* at 16.

2. Accuray's Objections

Accuray objects to Best Medical's extrinsic evidence because Best Medical "cites to dictionary definitions from English language dictionaries, some of which issued after the patent issued." Accuray's Response at 60. Accuray argues that "extrinsic evidence must relate to the meaning of claim terms to a person of ordinary skill in the art in 1996." *Id.*

B. Discussion

The parties' objections should be overruled. The Federal Circuit has "authorized district courts to rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Phillips*, 415 F.3d at 1317 (citations omitted). The Federal Circuit has viewed extrinsic evidence in general as "less reliable than the patent and its prosecution history in determining how to read claim terms," for several reasons that include:

- "extrinsic evidence by definition is not part of the patent and does not have the specification's virtue of being created at the time of patent prosecution for the purpose of explaining the patent's scope and meaning;"
- "while claims are construed as they would be understood by a hypothetical person of skill in the art, extrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent;"
- "extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence;"
- "there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question;" and
- "undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents."

Phillips, 415 F.3d at 1318-19 (citations omitted). Thus, "extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319. Nevertheless, a district court may "in its sound discretion," "admit and use such evidence." *Id.* If such evidence is admitted, "the court should keep

in mind the flaws inherent in each type of evidence and assess that evidence accordingly.” *Id.* Further, “[t]he sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law.” *Id.* at 1329.

C. Recommendation

In view of the foregoing, the master recommends that the Court overrule the parties’ objections.

VII. Indefiniteness

Accuray argues that claim 25 of the ‘283 patent is invalid as indefinite under 35 U.S.C. § 112 ¶ 2 because “it improperly combines two separate statutory classes of invention.” Accuray’s Reply at 59-60. Accuray also argues that claim 29 is invalid as indefinite because “the specification fails to disclose a specific structure (*i.e.*, algorithm) corresponding to each of the functional limitations recited in the claim.” *Id.* at 59-60. Each of Accuray’s contentions is discussed separately below.

A. Claim 25

1. The Parties’ Arguments

Accuray cites to *IPXL Holdings, L.L.C. v. Amazon.Com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005), and argues that:

[t]he preamble indicates that the patentees sought to claim ‘an apparatus’ including a ‘computer.’ However the claim limitations reference the use of the apparatus to perform a method step, e.g., to ‘computationally obtain a proposed radiation beam arrangement,’ ‘computationally change the proposed radiation beam arrangement iteratively,’ ‘chang[e] the beam weights,’ ‘incorporate a cost function at each iteration . . .’ and ‘to reject the change of the proposed radiation beam arrangement . . . and to accept the change of the proposed radiation beam arrangement . . .’

Accuray’s Response at 59. Thus, Accuray argues that in this case, as in *IPXL Holdings*, “it is unclear whether infringement of claim 25 occurs when one creates an apparatus that allows the user to ‘determine an optimized radiation beam arrangement,’ or whether infringement occurs when the user actually uses the apparatus to ‘determine an optimized radiation beam arrangement’ by

‘computationally obtain[ing] a proposed radiation beam arrangement,’ ‘computationally chang[ing] the proposed radiation beam arrangement iteratively,’ ‘changing the beam weights,’ ‘incorporat[ing] a cost function at each iteration . . .’ and ‘reject[ing] the change of the proposed radiation beam arrangement . . . and . . . accept[ing] the change of the proposed radiation beam arrangement’ ”

Id.

Best Medical replies that Accuray’s assertion that claim 25 is invalid as indefinite is “simply incorrect.” Best Medical’s Reply at 28. Best Medical argues that in *IPXL Holdings*:

[t]he Federal Circuit explained that, because the claim recited use by a user as a claim limitation, it is unclear if infringement would occur when one creates a system that allows a user to change the predicted transaction information, or when a user actually uses the system. In other words, the claim language ambiguously claimed both a system and a method for using the system. A potential seller of the claimed system would not know from the claim whether it might also be liable for contributory infringement if a buyer later performs the claimed method of using the system. Thus, the Federal Circuit found the claim invalid under § 112 (2).

Id. at 29.

Best Medical urges that this case is more akin to *Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1375 (Fed. Cir. 2008). Best Medical argues that in that case, “the Federal Circuit explained that apparatus claims are not necessarily indefinite for using functional language.*** Thus, functional language which merely describes the capability of the claimed structure will not render a claim invalid under *IPXL Holdings*.” *Id.* Best Medical contends that “the elements of Claim 25 do not recite both an apparatus and a method of using that apparatus” and that “each instance of the functional language pointed to by Accuray is preceded in the claim element by ‘a computer, adapted to’ or ‘the computer further adapted to.’ ” *Id.* at 30. Thus, Best Medical argues that “the functional language in Claim 25 merely describes the capabilities of the computer.” *Id.*

In reply, Accuray argues that Best Medical “misses the point.” Accuray’s Sur-Reply at 43. Accuray urges that “[t]he problem with claim 25, as in *IPXL*, is that the claim language does not apprise the public as to when infringement occurs. This is the hallmark of indefiniteness.” *Id.* (citations omitted). Accuray argues that:

the preamble indicates that the patentees sought to claim ‘an apparatus’ including a ‘computer.’ However the claim limitations references the use of the apparatus to perform a method step, e.g., to ‘computationally obtain a proposed radiation beam arrangement,’ ‘computationally change the proposed radiation beam

arrangement iteratively,’ ‘chang[e] the beam weights,’ ‘incorporate a cost function at each iteration . . .’ and ‘to reject the change of the proposed radiation beam arrangement . . . and to accept the change of the proposed radiation beam arrangement . . .’ Here, as in *IPXL*, it is unclear whether infringement of claim 25 occurs when an engineer creates an apparatus to ‘determine an optimized radiation beam arrangement’ that is capable of performing the recited functions, or whether infringement occurs when a clinician actually uses the apparatus to ‘determine an optimized radiation beam arrangement’ by ‘computationally obtain[ing] a proposed radiation beam arrangement,’ ‘computationally chang[ing] the proposed radiation beam arrangement iteratively,” “changing the beam weights,’ ‘incorporate[ing] a cost function at each iteration . . .’ and ‘reject[ing] the change of the proposed radiation beam arrangement . . . and . . . accept[ing] the change of the proposed radiation beam arrangement . . .’ *Id.* at 1383-84. Who is the potential infringer – the engineer or the clinician? Because claim 25 recites both an apparatus and a method for using that apparatus, the public is left to guess. [Best Medical] could not (or would not) answer this question in its Reply Brief.

Id. at 43-44.

2. Discussion

Indefiniteness is a question of law to be determined by the court. *IPXL Holdings*, 430 F.3d at 1381. Section 112(2), Title 35 of the United States Code, states that the “specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112 ¶ 2 (2000). A claim is considered indefinite if it does not reasonably apprise those skilled in the art of its scope. *IPXL Holdings*, 430 F.3d at 1383-84. Accuray is correct that a single claim may not recite both a system and a method for using that system. That is what the Federal Circuit held in *IPXL Holdings*. *Id.* at 1384. However, Best Medical is also correct that there is a difference between a claim which recites both an apparatus and a method, and apparatus claims using functional language. *Microprocessor Enhancement*, 520 F.3d at 1375.

In *IPXL Holdings*, the claim at issue read:

The system of claim 2 [including an input means] wherein the predicted transaction information comprises both a transaction type and transaction parameters associated with that transaction type, and the user uses the input means to either change the predicted transaction information or accept the displayed transaction type and transaction parameters.

IPXL Holdings, 430 F.3d at 1384 (emphasis added). The court held:

Thus, it is unclear whether infringement of claim 25 occurs when one creates a system that allows the user to change the predicted transaction information or

accept the displayed transaction, or whether infringement occurs when the user actually uses the input means to change transaction information or uses the input means to accept a displayed transaction. Because claim 25 recites both a system and the method for using that system, it does not apprise a person of ordinary skill in the art of its scope, and it is invalid under section 112, paragraph 2.

Id.; see *In re Katz*, 639 F.3d 1303, 1318 (Fed. Cir. 2011) (“In *IPXL*, this court addressed a claim that covered a system with “an input means” and required a user to use the input means. This court held that the claim was indefinite * * *.”); *HTC Corp. v. IPCom GmbH & Co.*, 667 F.3d 1270, 1277 (Fed. Cir. 2012) (“The *IPXL* claim, in other words, was ambiguous because it recited both a system that allowed a user to practice a method step and the user’s practicing the method step.”). Under that rationale, the Federal Circuit has held invalid claims such as the one at issue in *Technologies v. AOL LLC*:

3. A data transmitting device for transmitting signals corresponding to an incoming stream of bits, comprising:

first buffer means for partitioning said steam into frames of unequal number of bits and for separating the bits of each frame into a first group and a second group of bits;

fractional encoding means for receiving the first group of bits of each frame and performing fractional encoding to generate a group of fractionally encoded bits;

second buffer means for combining said second group of bits with said group of fractionally encoded bits to form frames of equal number of bits; trellis encoding means for trellis encoding the frames from said second buffer means; and

transmitting the trellis encoded frames.

641 F.3d 1331, 1339 (Fed. Cir. 2011) (“The first four elements of claim 3 * * * recite apparatus elements: buffer means, fractional encoding means, second buffer means, and trellis encoding means. The final element is a method: “transmitting the trellis encoded frame.’ ” (citations omitted)).

In *Microprocessor Enhancement*, however, the Federal Circuit reiterated that “apparatus claims are not necessarily indefinite for using functional language.” *Id.* at 1375. The apparatus claim at issue in that case read:

7. A pipelined processor for executing instructions comprising:

a conditional execution decision logic pipeline stage, a[t] least one instruction execution pipeline stage prior to said conditional execution decision logic pipeline stage;

at least one condition code;

said instructions including branch instructions and non-branch instructions and including opcodes specifying operations, operand specifiers specifying operands, and conditional execution specifiers;

the pipelined processor further including at least one write pipeline stage for writing the result(s) of each instruction to specified destination(s);

at least one of the instructions including a means for specifying writing said condition code with a condition code result;

the conditional execution decision logic pipeline stage performing a boolean algebraic evaluation of the condition code and said conditional execution specifier and producing an enable-write with at least two states, true and false;

said enable-write when true enabling and when false disabling the writing of instruction results at said write pipeline stage;

fetching means for fetching source operands specified by said operand specifiers;

operating means for performing the operation specified by said opcode;

condition code fetching means for fetching the condition code, when specified by the conditional execution specifier, at the pipeline stage immediately preceding the conditional execution decision logic;

the conditional execution decision logic pipeline stage, when specified by the conditional execution specifier, determining the enable-write using the boolean algebraic evaluation;

writing means for writing said non-branch instruction results to a destination specified by the operand specifiers and writing to the condition code when specified, if enable-write is true; and

said writing means further for discarding or not writing the non-branch instruction results and discarding or not writing the condition code, if enable-write is false.

Id. at 1371-72. The Federal Circuit found that claim 7 was “clearly limited to a pipelined processor possessing the recited structure and capable of performing the recited functions, and is thus not indefinite under *IPXL Holdings*.” *Id.* at 1375 (emphasis added).

Claim 25 does not run afoul of *IPXL Holdings*. Claim 25 recites “An apparatus for determining an optimized radiation beam arrangement * * *.” Col. 19, lines 66-67. On its face, claim 25 is drawn to an apparatus, not a method. The “apparatus” of claim 25 comprises a “computer” that is “adapted to” do various things:

a computer, adapted to computationally obtain a proposed radiation beam arrangement,

the computer further adapted to computationally change the proposed radiation beam arrangement iteratively, wherein the proposed radiation beam arrangement is changed by changing the beam weights,

the computer further adapted to incorporate a cost function at each iteration to approach correspondence of partial volume data associated with the proposed radiation beam arrangement to partial volume data associated with a pre-determined desired dose prescription, and

the computer further adapted to reject the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a lesser correspondence to the desired dose prescription and to accept the change of the proposed radiation beam arrangement if the change of the proposed radiation beam arrangement leads to a greater correspondence to the desired dose prescription to obtain an optimized radiation beam arrangement.

It is true that much of claim 25 is couched in functional language. However, that functional language describes what the computer is “adapted to” do. The parties’ arguments concerning the phrase “adapted to” reflects that. For example, Best Medical argues that the phrase “adapted to computationally obtain” means “the ‘computer’ (as construed above) is programmed to obtain a ‘proposed radiation beam arrangement’ (as construed below).” JCC at 9 (emphasis added). According to Accuray, that phrase means “[t]he computer is configured to run the Simulated Annealing algorithm (“SARP”) to calculate an array of proposed beam weights for the beam elements at each orientation during a given iteration of the simulated annealing (“SARP”) algorithm from partial volume data for each target and structure that is input into the computer by the user.” *Id.* at 9-10 (emphasis added). Unlike the claim in *IPXL Holdings*, claim 25 does not call both for a “computer adapted to” perform some function, and for using that computer. That is, claim 25 does

not call for both a computer and for user interaction with that computer, or otherwise require that the computer actually be used.

Unlike *IPXL Holdings*, therefore, claim 25 does not present ambiguity as to whether infringement of claim 25 occurs when one creates a computer that is adapted to perform the functions recited in claim 25, or whether infringement occurs when a user actually uses the computer adapted to perform the recited functions. *See Microprocessor Enhancement*, 520 F.3d at 1375.

Thus, regarding Accuray's confusion over whether infringement occurs "when an engineer creates an apparatus" or "when a clinician actually uses the apparatus," the answer is – both. Under 35 U.S.C. § 271(a), "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." The fact that one may infringe by making and also infringe by using does not render claim 25 indefinite. Again, *IPXL Holdings* involved a single claim calling for a "system" having an "input means," as well as for a user to use that "input means." Here, claim 25 does not call for both a computer and for using that computer, and thus does not fail to "apprise a person of ordinary skill in the art of its scope." Accuray's argument must therefore be rejected.

3. Recommendation

In view of the foregoing, therefore, the master recommends that the Court conclude that claim 25 is not invalid as indefinite under 35 U.S.C. § 112 ¶ 2.

B. Claim 29

Accuray argues that claim 29 is invalid as indefinite because "the specification fails to disclose a specific structure (*i.e.*, algorithm) corresponding to each of the functional limitations recited in the claim." *Id.* at 59-60. Specifically, Accuray argues that "the '283 patent specification, within its four corners, fails to describe any specific structure which performs the recited functions of claim 29," but that the '283 patent "purports to 'incorporate by reference' several publications by Webb that describe a computer programmed to run simulated annealing algorithms." " *Id.* at 60. Thus, Accuray argues that "[t]he specification itself does not describe any such structure, as required by § 112 ¶ 2." *Id.*

Best Medical argues that, "[e]ven a cursory review of the specification of the '283 Patent

belies Accuray's current assertion," because "[f]or every function recited in Claim 29, the '283 Patent describes a corresponding structure, as set forth element-by-element in Best Medical's Opening Claim Construction Brief." Best Medical's Reply at 30.

During the *Markman* Hearing, the Court decided that "the indefiniteness issues in connection with Claim 29, indefiniteness being under Section 112, Paragraphs 2 and 6, in the context of whether or not the disclosed algorithm is sufficiently disclosed to render the claim definite or rather not sufficiently disclosed to render the claims indefinite, the preference is to have that separately briefed by the parties in a separate motion." *Markman* Tr. at 157.

Accordingly, Accuray's indefiniteness argument with respect to claim 29 is not addressed in this report and recommendation.

VIII. Conclusion

This is the Special Master's Report and Recommendation on the issues referred to the master by the Court for resolution. Under Rule 53(f)(2), Fed. R. Civ. P.:

(2) Time To Object or Move to Adopt or Modify. A party may file objections to – or a motion to adopt or modify – the master's order, report, or recommendations no later than 21 days after a copy is served, unless the court sets a different time.

(emphasis added). Accordingly, the parties are encouraged to determine whether an order from the Court modifies the foregoing. Also, the parties are encouraged to review Rule 53(f)(3), (4), Fed. R. Civ. P., relating to the Court's *de novo* review of findings of fact and conclusions of law.

Although the parties must independently determine the applicable time period for filing objections, or motions to adopt or modify, the parties may, of course, seek further comment or clarification through motions directed to the master or the Court, as the Court may direct.

SIGNED this 7th day of September, 2012, in San Antonio, Texas.

/s/ Gale R. Peterson

Gale R. Peterson, Special Master

CERTIFICATE OF SERVICE

The undersigned has been appointed master in this cause pursuant to the Court's Order dated May 13, 2011 [Dkt. No. 56].

I hereby certify that on the 7th day of September, 2012, a true and correct copy of the foregoing document was electronically filed with the Clerk of the Court using CM/ECF and sent via Federal Express to the parties at the following addresses:

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and delivered an original and one copy via Federal Express to:

The Honorable Terrence F. McVerry
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U.S. Courthouse
700 Grant Street
Pittsburgh, PA 15219

/s/ Gale R. Peterson

Gale R. Peterson, Special Master